Summary of Safety and Clinical Performance – Adin's Dental Implants and Abutments – Class IIb

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device Identification and General Information

1.1. **Device trade name(s):** Dental Implants and abutments – See product list in appendix A

1.2. **Manufacturer's name and address**: Adin Dental Implant Systems Ltd., Industrial Zone Alon Tavor, POB 1128, Afula 1811101, Israel

1.3. **Manufacturer's single registration number (SRN):** IL-MF-000014625

1.4. **Basic UDI-DI:** See product list in appendix A

1.5. **Medical device nomenclature description/text:** EMDN No. - Dental Implants P01020101, Abutments P01020180

1.6. **Class of device:** IIb

1.7. **Year when the first certificate (CE) was issued covering the device:** Since 2006

1.8. **Authorized representative:** MedNet EC-REP GmbH, Address: Borkstrasse 10, 48163 Muenster, Germany, SRN: DE-AR-000000002.

1.9. **Notified Body:** MDC Medical Device Certification GmbH., Kriegerstraße 6, D-70191 Stuttgart, Germany, Single identification number: 0483.

2. Intended use of the device

2.1. Intended Purpose

Adin's dental implants and abutments are intended to be used in conjunction with each other during implant surgical placement in the maxillary and/or mandibular arches to support single-unit or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

2.2. Indications and Target Populations

Adin's dental implants are indicated for:

a. Replacing missing masticatory functional units (teeth) in single or multiple unit applications within the mandible or maxilla.

b. Single-stage or two-stage procedures (immediate or delayed loading). Immediate loading is recommended when good primary stability and appropriate occlusal loading are achieved.

c. Immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations.

Adin's dental abutments are indicated for:

a. Use in conjunction with the endosseous dental implant fixture to aid in prosthetic rehabilitation, to support single tooth prosthesis in the mandible or maxilla.

b. Use in conjunction with an endosseous dental implant fixture to aid in a healing phase prior to prosthetic rehabilitation in a partially or completely edentulous patients (Healing abutments and cover screws).

c. Use with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla (GRIP / Ball Attachment System).

d. Temporary cement-retained restoration of single crowns and bridges in the anterior and/or posterior regions for use up to 180-days (Temporary abutments).

e. Fabricating custom CAD/CAM abutments for single and multi-unit prostheses (Ti Base).

f. CAM fabrication of a single part (monolithic) customize titanium abutment or healing abutment (Ti Blanks).

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g. Multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design (TMA straight and up to 60° angulation).

h. Maxilla cases which are based on long (20, 22.5 & 25mm) with divergence greater than 32° and lower than 70° degrees from the implant axis, Use on implant with a diameter of 4.20-4.30 mm and Placement in the maxilla molar region (45°, 52° and 60° TMA).

i. Single unit restoration only. Configuration designated for single crown screw retain solution. (Single TMA straight and up to 30° angulation)

The target population is partially or fully edentulous patients (not recommended in children and under-aged patients, until growth has stopped and epiphyseal closure is completed).

Specific Restrictions:

- Narrow implants identified as Touareg CloseFit™ NP (3.0mmD), Touareg CloseFit™ UNP (2.75mmD) and One™ One-piece dental implants in diameter of 3.0mm are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.
- Short implant (less than 7mm long) should be used with straight abutments only.
- Maximal abutments angle is 58° (rounded to 60° on labeling).
- Abutment with post-height of less than 4mm should be used only for multi-unit loading restoration.

2.3. Contraindications and Limitations

- General contraindications associated with elective surgery should be observed.
- It is contraindicated placing abutments in the following cases in patients that are medically unfit for oral surgical procedures and in cases in which safe support of functional loads cannot be achieved.
- Do not use in cases of Allergy or hypersensitivity to response to Nylon, Titanium alloy (Ti, Al, V), CoCr Alloy (Co, Cr, Mo), Gold alloy (Au, Pt, Pd, Ir).
- Special attention, and a thorough evaluation of potential risks and benefits should be given to patients who exhibit underlying medical factors that might affect bone or soft tissue healing processes, for example:
    - Possible contraindications: chronic bleeding problems, psychological impairment, metabolic bone or connective tissue diseases, treatment with corticosteroids, certain cardiac and vascular diseases, tobacco usage, diabetes (uncontrolled), treatment with chemotherapeutic agents, chronic renal disease, poor patient oral hygiene, bruxing, alcoholism.
    - Temporary contraindications: systemic infection, local oral or respiratory infection.
    - Anatomical or pathological contraindications: insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone, both buccally and lingually to the most superior aspect of the implant body; inadequate bone height where proper implant placement would encroach on the mandibular canal; malignancies.
- Special accommodation should be practiced in patients with relative contraindications.
- The placement of dental implants is not recommended in children and under-aged patients, until growth has stopped and epiphyseal closure is completed.
- Local infections or pathologies, inadequate bone volume and/or quality as well as general diseases and treatments affecting bone and soft tissue healing may result in osseointegration failure, both immediately after surgery or at a later stage.
- Narrow platform implants (UNP & NP) are contraindicated for use at molar, premolar, and canine restorations.
- It is contraindicated to use UCLA Engaging Conical Connection NP 3.0 or UNP 2.75 in other positions than for lateral incisors in the maxilla or central and/or lateral incisors in the mandible.
- UCLA Engaging Conical Connection NP 3.0 or UNP 2.75 should not be used for multiple unit restorations.
- For TMA/sTMA:
    - Use of a TMA on a single implant restoration.
    - Use of a single TMA on a multi-unit restoration.
    - Use on TMA abutment with divergence greater than 20° from the insertion path axis is not applicable.

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- Distal cantilevers and bending moment on TMA.
- Uneven bite force distribution.
- Temporary Copying usage for final restoration solution (Temporary Copying maximum intraoral use is 180-days).
- TMA Restoration for UNP implant (Ø2.75mm) prosthetic platform.

- For TMA 45°, 52°, 60°:
  - Not appropriate where a non-rigid connection is required (e.g., removable denture).
  - Use of a TMA on a single implant restoration.
  - Use on implant with divergence lower than 32° or greater than 70° from vertical is not applicable.
  - Use on implants with a lower coronal diameter than 4.20mm.
  - Distal cantilevers and bending moment on TMA.
- For Ti Pre Milled MDTK Abutment Blank (Ti Blanks):
  - Only compatible connection geometry between Implants and abutments should be used.
  - Any post-processing of the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.
- For Adin Overdenture Attachment System:
  - Not appropriate where a totally rigid connection is required (e.g. Screw-retain restoration).
  - Use of a single implant.
  - Use on implant with divergence of greater than 20° from vertical is not applicable.
  - Use on Ultra Narrow implants.

3. Device Description

3.1. Device Description

Adin's products are dental implant systems consisting of endosseous dental implants and abutments made of biocompatible materials in various lengths and diameters. All implants (packaged with respective cover screws) are provided sterile using Gamma irradiation in SAL of at least 10^{-6}. The abutments (packaged with respective screws) are provided non-sterile and should be cleaned and steam-sterilized by the clinician before use at the clinic. All Adin's implants, abutments and respective screws are intended for single-use only.

The dental implant systems are following described:

Implants:

Adin's dental implant systems consist of endosseous dental implants and compatible abutments are made of Ti 6Al-4V ELI alloy that complies with ASTM F136-13(2021)e1, a biocompatible material, in various lengths and diameters.

Adin's implants are available in **AB/AE** (Alumina Oxide Blasted/Acid Etched) or **OsseoFix™** (Calcium Phosphate blast) surface treatment.

Adin's implant families are as follows:

- **Touareg™, Touareg™-S, Touareg™-OS** – Tapered implants with spiral tap which condenses the bone for immediate stability. The implants have two large variable threads and a tapered core for accurate implant placement. The implants have built-in platform switching. The prosthetic connection in these implants is a standard internal hex connection (RS) regardless of implant diameter. Touareg™ and Touareg™-S implants are featured in AB/AE surface treatment and Touareg™-OS features OsseoFix™ surface treatment.
- **Triple™** – Has similar design to Touareg™-S and Touareg™-OS implants. Has a triple-lead thread design that allows self-drilling, self-cutting and a very fast implant insertion. The prosthetic connection in Triple™ implants is a standard internal hex connection (RS) and the implants are featured in AB/AE surface treatment.

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- **Swell™** – Straight parallel-walled, slightly tapered implant with a V-shaped thread design. It has a double lead thread, a standard internal hex connection and is feature in AB/AE surface treatment.
- **Touareg CloseFit™** – Tapered-core implants with a spiral tap that promotes increased immediate stability. The implants have double lead thread design (2x1.2mm – for NP, RP and WP platforms) or triple lead thread design (3x1mm – for UNP platform). Prosthetic connection in these implants is a conical hex, unique for each diameter (UNP – 2.75mmD, NP – 3.0mmD, RP – 3.5mmD and WP – 4.3/5.0mmD). The implants are featured in OsseoFix™ surface treatment.
- **UniFit system** – Tapered-core implants with a spiral tap that promotes increased immediate stability same as Touareg CloseFit™. The implants have double lead thread design and a unified internal connection (Conical star connection) for several Touareg UniFit implants diameters and lengths. The external shape design is based on Touareg™ CloseFit RP/WP and Touareg™-OS implants and the usability is similar to Touareg™ CloseFit system.
- **One™** – A tapered-core spiral implant with integrated abutment post for minimally invasive surgery and immediate loading. The implants have a double lead thread design and are featured in AB/AE surface treatment.

Abutments:

Adin's abutments are placed into the dental implant and retained with a screw (the restoration is screw-retained on the implant level) to provide support for a prosthetic restoration. Prosthesis can be cement-retained, screw-retained to the abutment, or overdentures.

Adin's healing abutments are intended to be used with a dental implant to protect the inner configuration of the implant and maintain, stabilize and form the soft tissue during the healing process.

The abutments are provided non-sterile and are intended to be cleaned and steam-sterilized by the clinician prior to use according to the instructions given in the IFU accompanying the device.

Adin's abutments are made of the following raw materials:

Table 1 - Characterization of Adin's Dental Abutments

Component Name	Component Material
Healing Abutments, Cement Retained Abutments, Screw Retained Abutments, TitanFit™ Abutment (Base), Ti Bases, TMA Cementing Cone, Ti Blanks, Ball Attachment, Grip Abutment, Abutment Screw, Implant Cover screw, Metal Housing.	Titanium alloy Ti 6Al-4V ELI
GoldFit™ Abutment (Base)	Gold alloy: 60% Au, 19% Pt, 20% Pd, 1% Ir
CoCrFit™ Abutment (Base)	Cobalt-Chrome alloy, compliant with ISO 5832-12:2019 and ASTM F1537-20: Cobalt – max 60%, Chromium – 26-30%, Molybdenum – 5-7%
Burnout plastic casting sleeve (GoldFit™, TitanFit™, CoCrFit™)	POM-C (Polyoxymethylene)
Ball cap, Grip Retention males	Nylon (Polyamide 12)

Adin's abutments are divided into several groups per supported prosthetic restoration type:

- **Cement-retained abutments** – The abutment is retained with an abutment screw inside the implant, the prosthesis is cement-retained to the abutment. The abutments are straight or angulated (15°, 25° and 35° for RS platform and UF platforms, 15° and 25° for NP platform, 15° for UNP, RP and WP platforms)
- **Screw-retained abutments** – The abutment is screwed onto the implant and the prosthesis is screwed to the abutment with a prosthetic screw and come in the following variations:
    - **Trans mucosal abutment (TMA)** is indicated for multiple-unit, screw-retained restorations, and may be used in combination with an implant level framework design. The TMA are straight (0°)

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for all implants' platforms and angulated (RS and WP platforms: 17°, 30°, 45°, 52° and 60°; NP and RP platforms: 17° and 30°; UniFit platform: 17°, 30° and 45°).

- **Single TMA (sTMA)** is indicated for single crown screw retain solution, available in straight (0°) and up to 30° angulation for all implants' platforms.

The major restorative components of the screw-retained abutments:

- **TMA/sTMA Temporary Copying (Cylinder)** used for temporary restoration solutions (up to 180 days). It is adopted in height end externally cemented to restoration, while internally screw-retain directly to the TMA.
- **TMA/sTMA Cementing Cone** used for temporary and final restoration solutions. The abutment's prefabricated end is externally cemented to the restoration, while internally screw-retained directly to the TMA.
- **TMA/sTMA Healing Cap** is a temporary component that allows the final abutment to be used as healing abutment to allow the healing of the soft tissue.

- **Screw-retained or cement-retained abutments (UCLA abutments)** – are used for customized prosthetic restorations prepared by a dental technician in the laboratory utilizing a cast-on technique. The UCLA abutments consist of a metal base (made of either titanium, gold or cobalt-chrome alloy) compatible with implants' platform connection, a fully burn-out plastic sleeve and a titanium alloy abutment screw used to retain the restoration to the implant.
- **Prosthetic components for CAD/CAM restorations** – enable dentists and dental technicians to design and manufacture individual restorations supported by Adin's implants.
  - **Ti Bases** – allow restoration using superstructures and crowns manufactured from Zirconia and/or other dental metals while utilizing CAD/CAM technology to fit the components provided by Adin.
  - **TMA Cementing Cone** – Used as Ti Bases for multi-unit abutments for cementing/gluing CAD/CAM manufactured individual ceramic or metal restorations.
  - **Ti Blanks** (Ti Pre-Milled MDTK Abutment Blanks) – Used as a raw material for CAM fabrication of a single part (monolithic) individual titanium abutment. The design of the individual abutment is done digitally with CAD software.
- **Overdenture attachments** are used in conjunction with an endosseous dental implant fixture to retain overdentures during the prosthetic rehabilitation process.
  - **Ball Attachments** – Used in attachment-retained, tissue-supported multi-unit restorations where the patient is fully edentulous in the arch to be restored. The mechanism consists of a ball abutment secured to the implant by the integrated screw portion. A metal housing and ball cap mechanically retained within the housing, are fixed within the patient's denture.
  - **GRIP Implant Attachment** – The GRIP Implant Attachment System is a universal hinge, retention attachment for endosseous implants in the mandible or maxilla in order to restore masticatory function. The attachment system allows for the prosthesis to be removed and replaced by the patient.
    - **GRIP for TMA** – Designed to connect to both straight and angled TMA (Trans Mucosal Abutment).
    - **GRIP for bar** – Designed to connect to a splinted bridge, connected to both straight and angled TMA, other abutments or directly to implant.

Screws:

Single use titanium alloy Ti-6Al-4V ELI screws complying with ASTM F136-13 and ISO 5832-3:2021, intended to be used as follows:

- Adin's implant cover screws are intended to be used with the implant to protect the inner configuration of the implant during the healing process for a short-time use.
- Adin's abutment screws are intended to secure the abutment to the implant and supplied non-sterile, to be cleaned and steam-sterilized by the clinician prior to use according to the instructions given in the IFU.

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3.2. A Reference to Previous Generation(S) Or Variants If Such Exist, And A Description of The Differences

The Swell™ with its dual lead V-shaped tooth geometry and the industry traditional Alumina Oxide Blasted/Acid Etched surface treatment (AB/AE) and the Touareg, a conically shaped implant, developed in 2007. The Touareg-S improved upon Touareg design with a parallel shape and conical apex, this design enhanced immediate stability during placement.

Touareg-OS was added as a variation of the Touareg-S, with a calcium phosphate surface treatment (OsseoFix™) instead of AB/AE.

The Touareg CloseFit had platform modification and anodizing, the new design featured new conical hex connection and new NP, RP, WP abutment platforms.

The Triple is based on the Touareg-S, with added triple lead "Spiral" tooth, with a descending tooth thickness towards end.

The UniFit system which offered a unified internal connection for several Touareg CloseFit implants diameters and was a change on the design of an existing certified implant family: Touareg™ CloseFit (RP, WP).

3.3. Description of any accessories which are intended to be used in combination with the device

Adin's device does not fall under the definition of "accessory for a medical device" under the EU MDR article 2(2).

3.4. Description of any other devices and products which are intended to be used in combination with the device

Adin Dental implants and abutments are used in conjunction with each other. Adin's implant cover screws are intended to be used with the implant to protect the inner configuration of the implant during the healing process for a short-time use and Adin's abutment screws are intended to secure the abutment to the implant. Implants and abutments are used in conjunction with their respected screws. For implantation procedure, adapted drills are used and tools are necessary for connection of abutments to implants.

4. Risks and warnings

4.1. Residual risks and Undesirable Effects

Risk management process for dental implants and abutments was conducted with accordance to EN ISO 14971: 2019-A11:2021 and is part of the technical documentation.

Through the benefit-risk analysis and after mitigating all risks, it was concluded that no additional risks were induced. These residual risks are summarized below:

Table 2- Summary of Adin's Implant System Risk-benefit Analysis

Risk (Effect of Failure)	Degree of Probability	Mode of Failure	Cause of Failure	Risk Mitigation Activity
Bone tissue contamination/ inflammation, harm to the patient	Between 1:1,000,000 to 1:100,000, Very Low probability, Remote occurrence.	Implant failure	Use of non-sterile product (implant and/ or abutment and/ or tool)	1. IFU warning no to use the implant if the package is damaged. 2. Sterilization instructions in IFU (for abutments, tools, drills, surgical/prosthetic tool kit). 3. Labelling and instructions for single use only of abutments, implants. 4. On-going training and seminars.
Implant rejection, bone loss, harm to the patient, implant migration	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Implant failure and/or bone loss	Insufficient bone volume or bone quality	1. On-going training and seminars. 2. Surgical procedure instructions in user manual. 3. Warnings, precautions, contraindications and IFU for dental implants. 4. Warnings, precautions, contraindications and IFU for prosthetic components and tools, surgical/prosthetic tool kit. 5. Wide range of implants with different diameters and lengths is available - ADIN catalog.

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Risk (Effect of Failure)	Degree of Probability	Mode of Failure	Cause of Failure	Risk Mitigation Activity
Restoration failure, inability to use implant, implant rejection, bone tissue contamination/ inflammation, harm to the patient	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Superstructure fracture	Inadequate planning of restoration	1. On-going training and seminars - Restoration has to be performed by certified technician. 2. Prosthetic components and tools IFU. 3. Scab bodies, Ti-bases and TMA cementing cone IFU. 4. User manual instructions (intended use of the component). 5. Analytical calculations/numerical simulations that take into consideration safety factor of material strength for chosen material, which is sufficiently higher than material yield limit. 6. UniFit regular platform dynamic loading test - "worst case" fatigue test in accordance with ISO 14801. 7. Implant/abutment (stable and fit) connection design - Tolerance analysis of the components and the assembly.
Potential harm to the patient and risk of tissue, including (but not only) contamination/ inflammation damage to vital anatomic structures such as other teeth or implants, maxillary sinus or nerve damage up to permanent paranesthesia, and/or implant rejection.	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Inaccurate drilling or implant insertion	User error, user incompetence	1. Implantation procedure is performed by certified and licensed dentist. 2. On-going training and seminars. 3. Surgical/prosthetic tool kits IFU. 4. Instruction to use drill stopper and radiographic measurement tools, instructions for keeping minimal distance from natural dentition. 5. Wide range of implants diameters and length is available.
	Less than 1:1,000,000, Evidence that will likely not occur, cannot be distinguished from zero.	Implant failure	Inadequate preparation of the cavity (drilling)	1. On-going training and seminars. 2. Drilling protocol instructions in user manual (including recommendations to use drill stoppers). 3. Kit marking for correct usage - UniFit kits specification. 4. Drills marking (described in Adin's catalog). 5. Recommendation in user manual to use radiographic measurement tools for proper diagnose of drill depth. 6. UniFit implant system user evaluation - intended use validation.

4.2. Warnings and precautions

Warning:

- Adin's dental implants are intended for use only in the indicated applications.
- Appropriate training required prior to using the implant system and improper technique and/or inadequate training can lead to implant failure and/or loss of supportive bone.
- Dental implants must not be altered in any way.
- The use of electro-surgical instruments or lasers around metallic implants and their abutments is not recommended due to the risk of electric and/or heat conductivity.
- Implant mobility, bone loss, or chronic infection may indicate implant failure.
- If the implant becomes contaminated by the patient's body fluids in any way, the implant cannot be used in any other patient.
- Uncleaned and unsterile devices may pose a biological hazard due to tissue contamination. In order to prevent risks associated with such hazards, dispose used devices in accordance to applicable local laws and regulations or according to institutional protocol.

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- Do not reuse Implant, cover screws, temporary abutments and abutments, Reuse may lead to an increased risk for the product failure as functionality cannot be guaranteed and in addition, there is a risk of contamination.
- Proper clinical and radiographic evaluation of the patient should be performed prior to any implant placement.
- Implants should not be placed if there is not sufficient alveolar bone width and height to surround and sustain the implant.
- The label "Rx Only" refers to the following caution text: "Federal (USA) law restricts the sale of this device to, or on the order of, a licensed physician or dentist"
- MR Conditional: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant located outside of the RF coil.
- Design parameters for the Ti base's zirconia superstructure:
    - Minimum wall thickness – 0.5 mm
    - Minimum post height for single-unit restoration – 4.0 mm
    - Gingival height up to 4.5 mm
    - Maximum angulation - 20°
- Specific warnings for TitanFit/Plastic, GoldFit/Plastic, CoCrFit/Plastic (UCLA) Abutments:
    - Due to the small size of prosthetic components, special care must be taken to ensure that they are not swallowed or aspirated by the patient.
    - For Laboratory Technician: Do not inhale dust and vapors when machining. Ensure suitable air extraction/ventilation at the workplace and corresponding machinery
    - Interactions: Avoid occlusal and approximal contact between different alloy types. Do not use any solutions to remove investment material after casting. These solutions can attack the gold, titanium or cobalt chrome alloys and can damage the abutment.
- UCLA Abutments Design limits:
    - Minimum post height for single-unit restoration – 4.0 mm;
    - Not intended for angulation correction
    - Minimum Abutment wall thickness 0.5mm (after casting, from screw hole to outer abutment surface).
    - Not for individual tooth restorations with free end saddle
- Ti Blanks (Ti Pre Milled MDTK Abutment Blank) has to be inspected prior usage. The packing must be sealed without any visible damage. The following descriptions are not sufficient for the immediate use of the product. Dental skills and prior instructions of how to use the product are required.
- Ti Blanks Design limits:
    - Post height for single-unit restoration, Minimum 4.0 mm;
    - Abutment wall thickness, Minimum 0.5mm (screw hole to outer abutment surface).
    - Milled abutment height, Maximum 10 mm (above implant level)
    - Emergence profile height, Maximum 6mm
    - Abutment angulation up to 25°
    - Abutment angulation for UNP up to 15°
    - Abutment sharp edges should be avoided
    - Abutment should be rounded occlusally

Precautions:

- Used uncleaned and unsterile devices may pose a biological hazard due to tissue contamination. To prevent risks associated with such hazards, dispose used devices in accordance with applicable local laws and regulations or according to institutional protocol.

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- The surgical techniques required to place endosseous dental implants require specialized and complex procedures. Formal training for placement of implants is recommended.
- Important: determine local anatomy and suitability at the available bone for implant placement. Adequate radiographs direct palpation and visual inspection of the implant site are necessary prior to treatment, planning and use of Adin implants.
- Long implants (20, 22.5, 25mmL), placed in the maxilla, are only indicated for multiple restorations in splinted applications that utilize at least two implants. For using Adin's long implants, special attention needs to be paid to available bone volume and critical structures such as nerves, vessels and sinuses.
- Preoperative Considerations and Precautions:
    - Prior to any surgical procedure, patients must be carefully examined and evaluated to determine their medical, psychological and physical status. Attention should be given to factors that may put the patient at risk or factors that may affect bone or soft tissue healing.
    - Panoramic radiographs, as well as CT scans and other individual radiographs must be obtained to enable a complete evaluation of the dental and periodontal status, as well as for the evaluation of available bone for future implant placement.
    - A comprehensive dental treatment plan, including the locations, number and sizes of planned implants should be formulated based on a comprehensive clinical and radiographic evaluation.
    - Constant communication and collaboration between the dental surgeon, the restorative dentist and the dental laboratory technician are critical to ensure optimal outcomes.
    - Whenever applicable, a wax-up and a surgical guide should be used, to ensure correct positioning of dental implants.
    - Sufficient residual bone volume is necessary in order to achieve high primary and long-term success of dental implants. In cases of inadequate bone volume, bone augmentation procedures should be considered.
    - The number of implants and their diameters, lengths and positions in a specific case must take into account the planned prosthetic type and each individual's specific conditions and habits, such as bruxism or unfavorable jaw relations. Incorrect planning and implant placement may result in compromised esthetic results, undesirable restorative outcome, and increase risk of implant overload or mechanical failure.
- Intraoperative Considerations and Precautions:
    - The surgical placement of dental implants requires a high degree of precision and care.
    - Surgical procedures must always be performed using sterile instruments and tools.
    - All efforts must be made to minimize damage to both the soft and bone tissues during the surgical phase. Trauma, thermal injury and infection may result in implant failure or damage to the surrounding tissue.
    - Any divergence from the established surgical protocols increases the risk of osseointegration failure.
    - Loading and healing timing protocols should be determined based on bone quality and the implant's initial stability.
- Prosthetics Consideration sand Precautions
    - Adin implant systems support all established dental implant restorative options.
    - Successful restorative and esthetic outcomes require proper planning related to the number and position of the implants. Treatment planning should also take into account mechanical stress and occlusal force distribution, to prevent excessive transverse loads (particularly in immediate loading cases).
    - Passive fit of the prosthesis over implants and abutments is mandatory.
    - The use of abutments or other components not manufactured by Adin may damage Adin's implants. This, in turn, may lead to undesired prosthetic and/or esthetic results, and even to implant failure and damage to bone and soft tissues.
    - Adin short implants are to be used only with straight abutments.

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4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

Adin has reviewed adverse events as part of its post market surveillance (PMS) activities related to Adin's dental implant systems discussed in this clinical evaluation as well as to equivalent devices currently on the market, in order to evaluate whether any events that might affect the safety and performances have occurred.

Vigilance systems of several public health authorities were searched to identify and analyze reported recalls, adverse events and field safety corrective actions - No reported adverse events or recalls related to Adin's products were found.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable

The tables in appendix B summarize the equivalence comparison of Adin's dental implant systems, and the commercially available similar devices identified.

Adin's subject devices were found comparable with other commercially available devices in terms of:

- Same intended use (replacement of missing teeth to restore chewing function in patients).
- Same patient population (partially or fully edentulous patients),
- Same clinical application (surgical placement in jaw bone, immediate loading upon good primary stability and occlusal load)
- Same Material (surface treated titanium alloy for implants, abutments from titanium, gold and cobalt chrome)
- Dimensions (diameters and lengths variations of the implants are similar).

In light of the above it was concluded by Adin that the subject devices are equivalent to the similar commercially available products

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable.

5.3. Summary of clinical data from other sources, if applicable

Adin clinical data were obtained from long term PMCF information and users' feedback. Being Adin's Implants and abutments well-established devices with sufficient clinical data and experience since the products were first CE marked (April 2006), additional Clinical studies were not conducted by Adin. Adin can demonstrate equivalence through public clinical and commercial information published by the manufacturers of the equivalent products, taking into consideration the technical, biological and clinical characteristics, as required in Annex XIV Section 3 of the EU MDR.

As part of PMS activities, Adin reviews and analyzes all received customer complaints in accordance with Adin's SOP 8.2.2.00.00 and the revealed no trending issues.

The survival rate of Adin's implant systems is in line with stated in scientific publications for implants by other manufacturers currently on the market (The number of reports of failed implants per year constitutes 1.28% - 1.83%).

Analysis of these complaints shows that the majority concerns implantation failure by biological reasons, e.g., mobility, failure to osseointegrate, fibrointegration, infection, pain, no primary stability, etc.

The clinical performance of Adin's dental implants and abutments is well-established through gathered PMS and PMCF activities, and that various clinical aspects of dental implant systems are well covered in published literature.

The literature review conducted to identify publications through a search of the scientific literature pertaining to the performance and safety of Adin's dental implants and abutments and show favorable clinical outcome using Adin's (or comparable to Adin's) implants and abutments. (See Bibliography in Appendix D)

5.4. An Overall Summary of The Clinical Performance and Safety

Adin's dental implants systems were assessed based on the following tests, performed according to state-of-the-art standards (EU harmonized standards were use where available) in order to verify and validate the safe clinical use of the devices:

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- **Biocompatibility Tests** were performed on Adin's dental implants and abutments to protect patients from undue risks arising from biological hazards associated with materials of manufacture and final device. Titanium implants (with OsseoFix™ and AB/AE surface treatments) and abutments were tested for cytotoxicity using guidelines of EN ISO 10993-5:2009, skin sensitization and irritation using guidelines of EN ISO 10993-10:2013.

  Additional materials used for production of abutments (gold alloy and cobalt chrome alloy) were also subjected to various biocompatibility tests (cytotoxicity, irritation and systemic toxicity for gold alloy, per EN ISO 10993-5:2009, EN ISO 10993-10:2013 and ISO EN ISO 10993-11:2018 and cytotoxicity and chemical characterization per EN ISO 10993-5:2009 and EN ISO 10993-18:2020. Based on test results it was concluded that all materials are biocompatible when used under recommended intended use.

- **Fatigue Testing –** Fatigue tests of all Adin's dental implant systems assembled with abutments were tested using fatigue test in accordance with EN ISO 14801:2016. Per standard requirements, 'worst-case' implant-abutment assembly was chosen for the test. Implants with smallest diameters and cross-sections at implant embedding level were selected and tested as representatives of each implant family - Results of the test showed that all implants are within approved Adin's specification.

- **Gamma Sterilization Validation -** Adin's dental implants are provided sterile using gamma radiation, packaged in sterile-barrier system packaging that went through gamma sterilization validation in accordance with VDmax 20kGy method per EN ISO 11137-2:2015 standard in conjunction with ISO/TS 13004:2013. Results showed that Sterile Assurance Level (SAL) of at least 10^{-6} is achieved under routine sterilization process which is revalidated using dose audit performed quarterly per EN ISO 11137-2:2015 requirements.

- **Package Integrity Validation for the Duration of Shelf Life –** Adin has two Implants sterile-barrier packaging configurations (with and without a fixture mount) with identical sterile barrier system – outer tube, color coded cap (represent implant diameter).

  The sterile barrier packaging is labeled and packaged in a single unit labeled cardboard box that serves as the secondary packaging with the IFU and two additional peel-off identification labels as the one affixed to the box.

  Integrity of sterile-barrier packaging employed by Adin for sterile dental implants was validated in accordance with EN ISO 11607-1:2020.

  Based on results for performed tests it was concluded that integrity of sterile-barrier packaging as well as sterility of the implants remain through shelf life defined as five years and through transportation processes.

  Adin’s Abutments are provided non-sterile as a stand-alone device packed together with its compatible screw in a single-unit pouch packaging intended to keep the device identified and protected from dust and for transportation only.

  Shelf life is defined in the relevant IFU as to grinding aspects due to usage period.

  Transportation validation of Adin's implant systems devices was validated for integrity in transportation simulation testing in accordance with ASTM D4169-16 and ASTM D4332-14.

  All products configurations meet the acceptance criteria that were defined for the test.

- **Steam-Sterilization Validation for Non-Sterile Devices –** Adin’s abutments are provided non-sterile, for single use. The end user (clinician) is instructed to clean and steam-sterilize the abutments prior to clinical use. Steam-sterilization method recommended by Adin was validated in accordance with EN ISO 17665-1:2006. Based on results of this validation study it was concluded that steam-sterilization method recommended by Adin achieves SAL of at least 10^{-6}.

5.5. Ongoing or planned post-market clinical follow-up

Post Marketing Clinical Follow-up (PMCF) Plan, a decision is made on conducting PMCF study based on data collected through PMS activities, in order to confirm clinical performance and safety of the device. The decision about conducting PMCF will be accepted if the criteria for such study are met per the PMCF approved plan.

Based on PMS data for 2023 as conducted by Adin, potential adverse events reviewed through vigilance databases as well as other criteria from the PMCF plan, it was determined that no new risks in regards with device's clinical safety and effectiveness were raised.

6. Possible diagnostic or therapeutic alternatives

Not applicable.

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7. Suggested profile and training for users

All the intended users are licensed dentists or lab technicians who are specialized in the dental implant field and as such have the technical knowledge, experience, education and the necessary training. In addition, Adin provided intended users with the necessary information (warning, instruction for use, contraindication) through IFU, user manuals and additional training/guidance when deemed necessary.

8. Reference to any harmonized standards and CS applied

See list of applied standards and common specifications in Appendix C.

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
1.0	22.05.2022	First edition	☒Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
2.0	03.06.2024	Section 2.2 – Indication addition for Ti bases, Ti blanks, TMAs and temporary abutments. Section 2.3 – alloys type added in Allergy or hypersensitivity. added contraindication for TMA, Ti blanks and overdentures attachment system. Scan bodies were removed. Section 3.1 – addition of TMA's component description. Section 4.2 – addition of design limits for UCLA abutments and Ti base's zirconia superstructure. Ti blank design limits were clarified. Section 5.3 - demonstration of equivalence was clarified Annex A – added missing screw retained abutments and corrected the Basic UDIs Appendix C – Updated standards revisions	☒ Yes Validation language: English ☐ No

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Appendices

Appendix A - List of Class IIb Products covered under Adin Dental Implant Systems Ltd.

The list of Class IIb Products is hereby presented, the full detailed list can be found Adin Declaration of conformity for Adin's Dental Implants and abutments class IIb.

Diameter (mm)	Length (mm)	Platform Connection	Basic UDI-DI
Dental Implants – GMDN 55849			
Swell™ Dental Implant			
3.3, 3.75	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.42mm	729010515SwellImpJH (Mounted version) 729010930SwellImpLL (Mountless version)
4.2, 5.0, 6.0	6.25, 8, 10, 11.5, 13, 16, 18		
Touareg™/ Touareg™-X Dental Implant			
3.75 (Touareg)	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.42mm	729010515TouaregImpXR (Mounted version) 729010930TouaregImp2F (Mountless version)
4.2, 5.0, 6.0 (Touareg™-X)	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.42mm	729010515TouaregXImpGS (Mounted version) 729010930TouaregXImpJX (Mountless version)
Touareg™-S Dental Implant			
3.5, 3.75	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.42mm	729010515TouaregSImpFP (Mounted version) 729010930TouaregSImpHU (Mountless version)
4.2, 5.0, 6.0	6.25, 8, 10, 11.5, 13, 16, 18		
Touareg™-OS Dental Implant			
3.5, 3.75	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.4mm	729010515TouaregOSImp3T (Mounted version) 729010930TouaregOSImp5Y (Mounted version) 729010930TouaregOSImp5Y (Mountless version)
4.2	6.25, 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25		
5.0, 6.0	6.25, 8, 10, 11.5, 13, 16, 18		
Touareg CloseFit™ UNP Dental Implant (Mountless)			
2.75	10, 11.5, 13, 16, 18	Conical hex, UNP 2mm	729010515CloseFitUNPImp6K
Touareg CloseFit™ NP Dental Implant			
3.0	8, 10, 11.5, 13, 16, 18	Conical hex, NP 2mm	729010515CloseFitNPImp5F (Mounted version) 729010930CloseFitNPImp8A (Mountless version)
Touareg CloseFit™ RP Dental Implant			
3.5	8, 10, 11.5, 13, 15, 18	Conical hex, RP 2.24mm	729010515CloseFitRPImp6T (Mounted version) 729010930CloseFitRPImp9N (Mountless version)
Touareg CloseFit™ WP Dental Implant			
4.3	8, 10, 11.5, 13, 15, 18, 20, 22.5, 25	Conical hex, WP 2.64mm	729010515CloseFitWPImp8J (Mounted version) 729010930CloseFitWPImpBD (Mounted version) 729010930CloseFitWPImpBD (Mountless version)
5.0	8, 10, 11.5, 13, 15, 18		
Triple ™ Spiral Dental Implant			
3.5, 3.75	8, 10, 11.5, 13, 16, 18	Standard internal hex, RS 2.4mm	729010515TripleImpL3 (Mounted version) 729010930TripleImpN4 (Mountless version)
4.2	6.25, 8, 10, 11.5, 13, 16, 18		
5.0, 6.0	6.25, 8, 10, 11.5, 13, 16		
One™ Dental Implant			
3.0, 3.3, 3.6, 4.2, 5.0	10, 11.5, 13, 15	N/A, monoblock implant (integrated abutment)	729010515OneImpWE
Touareg UniFit Implant			
3.5	8, 10, 11.5, 13, 16, 18	Conical star 2.4mm	729010930UniFitImp

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Diameter (mm)	Length (mm)	Platform Connection	Basic UDI-DI
3.75	8, 10, 11.5, 13, 16, 18, 20, 22.5, 25		
4.3, 5.0	6, 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25		
6.0	6, 8, 10, 11.5, 13		

Diameter (mm)	Length (mm)	Platform Connection	Basic UDI-DI
Healing Abutments – GMDN 44880			
Slim Healing abutment			
3.5	6.70, 7.70, 8.70, 9.70, 10.70, 11.70	RS	729010515RSHealingAbut9T 729010930RSHealingAbutCN
3.5	6.80, 7.80, 8.80, 9.80, 10.80	UniFit	729010930UFHealAbutZD
2.75	6.85, 7.85, 8.85, 9.85, 10.85	UNP	729010515UNPHealingAbutP9
3	6.55, 7.55, 8.55, 9.55, 10.55	NP	729010515NPHealingAbutZ5
3.5	6.80, 7.80, 8.80, 9.80, 10.80	RP	729010515RPHealingAbut6C
4	7.30, 8.30, 9.30, 10.30, 11.30	WP	729010515WPHealingAbutCY
Healing Abutment			
4.5	6.85, 7.85, 8.85, 9.85, 10.85, 11.85	RS	729010515RSHealingAbut9T 729010930RSHealingAbutCN
4.5	6.80, 7.80, 8.80, 9.80, 10.80	UniFit	729010930UFHealAbutZD
4	7.10, 8.10, 9.10, 10.10, 11.10	UNP	729010515UNPHealingAbutP9
4.5	6.50, 7.50, 8.50, 9.50, 10.50	NP	729010515NPHealingAbutZ5
4.5	6.80, 7.80, 8.80, 9.80, 10.80	RP	729010515RPHealingAbut6C
5.5	7.30, 8.30, 9.30, 10.30, 11.30	WP	729010515WPHealingAbutCY
Wide Healing Abutment			
6	6.80, 7.80, 8.80, 9.80, 10.80, 11.80	RS	729010515RSHealingAbut9T 729010930RSHealingAbutCN
5.5	6.80, 7.80, 8.80, 9.80, 10.80	UniFit	729010930UFHealAbutZD
Slim Conical Healing Abutment			
3.5	7.30, 8.30, 9.30, 10.30, 11.30	UniFit	729010930UFHealAbutZD
Conical Healing Abutment			
4.5	7.30, 8.30, 9.30, 10.30, 11.30	UniFit	729010930UFHealAbutZD
4	6.85, 7.85, 8.85, 9.85, 10.85	UNP	729010515UNPHealingAbutP9
4.5	6.85, 7.85, 8.85, 9.85, 10.85	NP	729010515NPHealingAbutZ5
4.5	7.15, 8.15, 9.15, 10.15, 11.15	RP	729010515RPHealingAbut6C
5.5	7.85, 8.85, 9.85, 10.85, 11.85	WP	729010515WPHealingAbutCY
Wide Conical Healing Abutment			
5.5	7.30, 8.30, 9.30, 10.30, 11.30	UniFit	729010930UFHealAbutZD
TMA Healing Cap			
4.9	5.50		729010515TMAHealCapUK

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Diameter (mm)	Length (mm)	Platform Connection	Basic UDI-DI
	7.00	N/A, can be used in TMA of all implant platforms	729010930TMAHealCapX6
Single TMA Healing Cap			
4.9	5.50	N/A, can be used in Single TMA of all implant platforms	729010930STMAHealCapY3

Basic UDI-DI	Trade Name	GMDN
Cement Retained Abutments		
729010515RSStrTempAbut3N	RS Temporary Abutment (Straight Cylindrical Titanium Abutment)	44880
729010515UNPTempAbutSY	UNP Temporary Abutment	
729010515NPTempAbutPP	NP Temporary Abutment	
729010515RPTempAbutTB	RP Temporary Abutment	
729010515WPTempAbutXU	WP Temporary Abutment	
729010930UFTempAbutRF	UniFit Temporary Abutment	
729010515RSStrTitanAbutAA	RS Straight Titanium Abutment	44879
729010515RS1PScrwInAbutLN	RS One Piece Screw-in Abutment	
729010515RSAnglTitAbut9F	RS Angled Titanium Abutment	
729010515UNPStrTitAbutEZ	UNP Straight Abutment	
729010515UNP1ScrwInAbutPW	UNP CloseFit™ One Piece Screw-in Abutment	
729010515UNPAnglTitAbutNV	UNP CloseFit™ Angled Abutment	
729010515NPStrTitAbutUH	NP Straight Abutment	
729010515NPAnglTitAbutYR	NP CloseFit™ Angled Abutment	
729010515RPStrTitAbutZ5	RP Straight Abutment	
729010515RPAnglTitAbut5Y 729010930RPAnglTitAbut8T	RP Angled Abutment	
729010515WPStrTitAbut6Z	WP Straight Abutment	
729010515WPAnglTitAbutCD 729010930WPAnglTitAbutF8	WP Angled Abutment	
729010930UFStrTitAbutV3	UniFit Straight Abutment	
729010930UFAnglTitAbutYZ	UniFit Angled Abutment	
Screw Retained Abutments		
729010515RSStrTMAUP	RS Straight Trans Mucosal Abutment	44879
729010930RSStrSTMARH	RS Straight Single TMA	
729010515RSAnglTMAC3 729010930RSAnglTMAE4	RS Angled Trans Mucosal Abutment	
729010930RSAnglSTMAJ5	RS Angled Single TMA	
729010515NPStrTMAQQ	NP Straight Trans Mucosal Abutment	
729010930NPStrSTMALU	NP Straight Single Trans Mucosal Abutment	
729010515NPAnglTMA7E	NP Angled Trans Mucosal Abutment	
729010930NPAnglSTMACC	NP Angled Single Trans Mucosal Abutment	
729010515RPStrTMAT4	RP Straight Trans Mucosal Abutment	
729010930RPStrTMAV7	RP Straight Single Trans Mucosal Abutment	

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Basic UDI-DI	Trade Name	GMDN
729010515RPAnglTMAAA	RP Angled Trans Mucosal Abutment	
729010930RPAnglSTMAFY	RP Angled Single Trans Mucosal Abutment	
729010515WPStrTMAW3	WP Straight Trans Mucosal Abutment	
729010930WPStrSTMATB	WP Straight Single Trans Mucosal Abutment	
729010515WPAnglTMADV 729011677WPAnglTMAPX 729010930WPAnglTMAFW	WP Angled Trans Mucosal Abutment	
729010930WPAnglSTMALH	WP Angled Single Trans Mucosal Abutment	
729010930UFStrTMARN	UniFit Straight Trans Mucosal Abutment	
729010930UFStrSTMAKX	UniFit Straight Single Trans Mucosal Abutment	
729010930UFAnglTMA8J	UniFit Angled Trans Mucosal Abutment	
729010930UFAnglSTMABH	UniFit Angled Single Trans Mucosal Abutment	
729010515RSFlatConAbut49	RS Flat Connection Abutment	
729010515NPFlatConAbutTK	NP Flat Connection Abutment	
729010515RPFlatConAbutYP	RP Flat Connection Abutment	
729010515WPFlatConAbut77	WP Flat Connection Abutment	
729010930UFFlatConAbutTT	UniFit Flat Connection Abutment	
729010515RSConAbutF7	RS Connection Abutment	
729010515FlatConAccesTL	Flat Connection Titanium Gluing Ring	
	Flat Connection Temporary Cylinder Sleeve	
729010515TMATempAbutEB	TMA Titanium Temporary Copying	44880
729010930TMATempAbutGG	Single TMA Titanium Temporary	
Cement or Screw Retained Abutments (UCLA Abutments)		
729010515RSTitanFitAbutSR	RS Titanium / Plastic Abutment (TitanFit™)	44879
729010515NPTitanFitAbutHJ	NP Titanium / Plastic Abutment (TitanFit™)	
729010515RPTitanFitAbutNW	RP Titanium / Plastic Abutment (TitanFit™)	
729010515WPTitanFitAbutVM	WP Titanium / Plastic Abutment (TitanFit™)	
729010930UFTitanFitAbutHG	UniFit Titanium / Plastic Abutment (TitanFit™)	
729010515RSGoldFitAbut7K 729010930RSGoldFitAbutAE	RS Gold / Plastic Abutment (GoldFit™)	
729010930UNPGoldFitAbutQC	UNP Gold / Plastic Abutment (GoldFit™)	
729010515NPGoldFitAbutWV	NP Gold / Plastic Abutment (GoldFit™)	
729010515RPGoldFitAbut44	RS Gold / Plastic Abutment (GoldFit™)	
729010515WPGoldFitAbutAH	WP Gold / Plastic Abutment (GoldFit™)	
729010930RSCoCrFitAbutLV	RS Cobalt Chrome / Plastic Abutment (CoCrFit™)	
729010930UNPCoCrFitAbut2W	UNP Cobalt Chrome / Plastic Abutment (CoCrFit™)	
729010930NPCoCrFitAbutCA	NP Cobalt Chrome / Plastic Abutment (CoCrFit™)	
729010930RPCoCrFitAbutHE	RP Cobalt Chrome / Plastic Abutment (CoCrFit™)	
729010930WPCoCrFitAbutPT	WP Cobalt Chrome / Plastic Abutment (CoCrFit™)	
729010930UFCoCrFitAbut9P	UniFit Cobalt Chrome / Plastic Abutment (CoCrFit™)	
Prosthetic Components for CAD/CAM		

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Basic UDI-DI	Trade Name	GMDN
729010930TMACementConeDT	TMA Cementing Cone	44879
729010930RSTiBaseAbut8T	RS Ti Base	
729010930UNPTiBaseAbutLD	UNP Ti Base	
729010930NPTiBaseAbutZ7	NP Ti Base	
729010930RPTiBaseAbut5W	RP Ti Base	
729010930WPTiBaseAbutBP	WP Ti Base	
729010930UFTiBaseAbutXL	UniFit Ti Base	
729010930RSTiBlankAbut6C	RS Ti Pre Milled MDTK Abutment Blank (RS Ti Blank)	
729010930UNPTiBlankAbutLA	UNP CloseFit™ Ti Pre Milled MDTK Abutment Blank (UNP Ti Blank)	
729010930NPTiBlankAbutVN	NP CloseFit™ Ti Pre Milled MDTK Abutment Blank (NP Ti Blank)	
729010930RPTiBlankAbut2V	RP CloseFit™ Ti Pre Milled MDTK Abutment Blank (RP Ti Blank)	
729010930WPTiBlankAbut9A	WP CloseFit™ Ti Pre Milled MDTK Abutment Blank (WP Ti Blank)	
729010930UFTiBlankAbutT3	UniFit Ti Pre Milled MDTK Abutment Blank (UniFit Ti Blank)	
Overdenture's Attachments		
729010515RSBallAttach6R	RS Ball Attachment	44879
729010515UNPBallAttachHM	UNP Ball Attachment	
729010515NPBallAttachX5	NP Ball Attachment	
729010515RPBallAttach3U	RP Ball Attachment	
729010515WPBallAttach9M	WP Ball Attachment	
729010930UFBallAttachXP	UniFit Ball Attachment Abutment	
729010515BallCapsT2	Plastic Ball Caps	44880
729010515MetalHousingQY	Titanium Ball Cap (Metal Housing)	
729010930RSCylindGripX7 729010515RSCylindGripV2	Grip RS Abutment	44879
729010515NPCylindGripMH 729010930NPCylindGripPN	Grip NP Abutment	
729010515RPCylindGripS5 729010930RPCylindGripUA	Grip RP Abutment	
729010515WPCylindGripXW 729010930WPCylindGrip26	Grip WP Abutment	
729010930TMACylindGripRS	Grip for TMA	
729010930GripAccessAG	Grip for Bar, M2 thread	44879
	Grip housing, 4 pack	
	Grip Retention - Extra Light (Blue), 4 pack	
	Grip Retention - Light (Pink), 4 pack	
	Grip Retention - Regular (Clear), 4 pack	
	Grip Extended Range Retention - Zero (Gray), 4 pack	
	Grip Extended Range Retention - Extra Light (Red), 4 pack	
	Grip Extended Range Retention - Light (Orange), 4 pack	
	Grip Extended Range Retention - Regular (Green), 4 pack	
	Grip processing set	

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Basic UDI-DI	Trade Name	GMDN
	Grip processing set (Blue & Pink)	
	Grip Extended Range processing set	
Screws		
729010515ImpCoverscrews6R 729010930ImpCoverscrewsA4	Implant Cover screws	44880
729010930UFAbutScrwM7	UniFit Abutment Screw	
729010515RSAbutScrewZS	RS Abutment Screw	61647
729010515RSTMARetScrwKL	RS TMA Retaining Screw	
729010515UNPAbutScrwNQ	UNP Abutment Screw	
729010515NPAbutScrwKF	NP Abutment Screw	
729010515NPTMARetScrwC3	NP TMA Retaining Screw	
729010515RPAbutScrwP3	RP Abutment Screw	
729010515RPTMARetScrwGP	RP TMA Retaining Screw	
729010515WPAbutScrwTL	WP Abutment Screw	
729010515WPTMARetScrwNG	WP TMA Retaining Screw	
729010930UFTMARetScrwCM	UniFit TMA Retaining Screw	
729010515TMAProsthScrwA9	TMA Prosthetic Screw	
729010515FlatConnecScrw9K	Flat Connection Titanium Retaining Screw	
729010930TMAProsthScrwD4	TMA Scan Body Screw	61641

-- END OF PRODUCT LIST –

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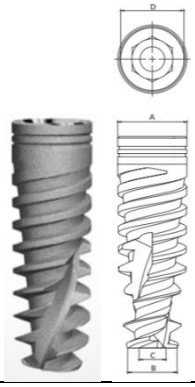
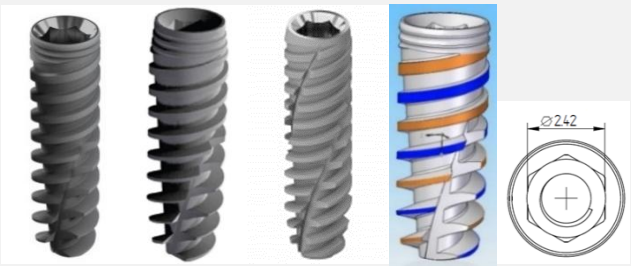
Appendix B – Summery of Adin's Dental Implant system and Similar Devices

Product / Feature	Similar Device #1 – Spiral™ (SPI) Implant by Alpha-Bio Tec	Adin's Touareg™, Touareg™-S and Triple dental implants
Intended use	Alpha-Bio Tec implants are intended for rehabilitating fully or partially edentulous patients. Dental implants are intended to be used in a manner that they will integrate the bone (osseointegration).	Adin's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Surface treatment	Sandblasting and acid etching surface treatment	AB/AE (alumina oxide blasting / acid etching)
Basic design	Spiral, tapered with double threads	Spiral, tapered, double-lead thread
Implant-abutment connection	Internal hex	Internal hex
Diameters (mm)	3.3, 3.75, 4.2, 5, 6	3.5, 3.75, 4.2, 5, 6
Lengths (mm)	8, 10, 11.5, 13, 16 (for 3.3 – 5mmD) 8, 10, 11.5, 13 (for 6mmD)	8, 10, 11.5, 13, 16, 18 (for 3.5-3.75mmD) 6.25, 8, 10, 11.5, 13, 16, 18 (for 4.2mmD) 6.25, 8, 10, 11.5, 13, 16 (for 5mmD) 6.25, 8, 10, 11.5, 13 (for 6mmD)
Sterility	Sterile using gamma radiation	Sterile using gamma radiation
Prosthetic components	Healing abutments. Cement-retained abutments (straight and angulated: 15°, 25°). Screw-retained abutments (straight and angular: 17°, 30°). Overdenture restorations (straight and angular).	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35° for RS). Screw-retained abutments (straight and angulated: 17°, 30° and 45° for RS). Overdenture restorations (straight). CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks).
CE-Marked	Yes	Yes
Illustrations		

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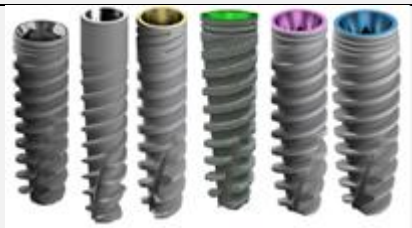
Product / Feature	Similar Device #2 – I5 Conical Implant by A.B. Dental	Adin's Touareg™-OS, Touareg CloseFit™ (UNP, NP, RP and WP) and Touareg UniFit dental implants
Intended use	A.B. Dental Devices' implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. Implants for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	Adin's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Narrow implants identified as Touareg CloseFit™ NP (3.0mmD) and Touareg CloseFit™ UNP (2.75mmD) are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Surface treatment	Special blasting with calcium phosphate	OsseoFix™ (calcium phosphate blasting)
Basic design	Spiral, tapered with double threads	Spiral, tapered, double-lead thread
Implant-abutment connection	Internal hex	Internal hex in Touareg™-OS, Conical hex in Touareg CloseFit™ UNP, NP, RP and WP implants, Conical star in Touareg UniFit implants.
Diameters (mm)	3, 3.2/3.3, 3.5, 3.75, 4.2, 4.5, 5, 6	3.5, 3.75, 4.2, 5, 6 – Touareg OS 2.75, 3, 3.5, 4.3, 5 – Touareg CloseFit™ 3.5, 3.75, 4.3, 5, 6 - Touareg UniFit
Lengths (mm)	10, 11.5, 13, 16 (for 3-3.5mmD), 8, 10, 11.5, 13, 16 (for 3.75 and 4.2mmD) 6, 8, 10, 11.5, 13, 16 (for 4.5 – 6mmD)	Touareg™-OS: 8, 10, 11.5, 13, 16, 18 (for 3.5-3.75mmD) 6.25, 8, 10, 11.5, 13, 16, 18 (for 4.2mmD) 6.25, 8, 10, 11.5, 13, 16 (for 5mmD) 6.25, 8, 10, 11.5, 13 (for 6mmD) Touareg CloseFit™: 10, 11.5, 13, 16, 18 (for 2.75 and 3.0mmD). 8, 10, 11.5, 13, 15, 18 (for 3.4, 4.3 and 5.0mmD). Touareg UniFit: 8, 10, 11.5, 13, 16, 18 (for 3.5mmD). 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25 (for 3.75mmD) 6.0, 8, 10, 11.5, 13, 16, 18, 20, 22.5, 25 (for 4.3 and 5.0mmD). 6.0, 8, 10, 11.5, 13 (for 6.0mmD).
Sterility	Sterile using gamma radiation	Sterile using gamma radiation
Prosthetic components	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35°, 45°) Composed abutments – Plastic Sleeve with metal base (titanium, cobalt chrome or gold) Screw-retained abutments (straight and angular: 17°, 30°) Overdenture restorations (straight and angular) Lab products (CAD/CAM bases, individual block for milling)	Healing abutments. Cement-retained abutments (straight and angulated: 15°, 25°, 35° for RS and UF platforms, 15°, 25° for NP platform, 15° for UNP, RP and WP platforms) UCLA Abutments – plastic casting sleeve and metal base (titanium, gold or cobalt chrome). Screw-retained abutments (straight and angulated: 17°, 30°, 45° for RS and UF, 17°, 30° for NP, RP and WP) Overdenture restorations (straight). CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks).
CE-Marked	Yes	Yes
Illustrations		

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Product / Feature	Similar Device #3 – Tapered Screw-Vent Implant by Zimmer Biomet	Adin's Swell™ Dental Implants
Intended use	Tapered Screw-Vent Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load.	Adin's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Surface treatment	Surface grit-blasting by hydroxylapatite followed by washing in acid to remove residual blasting material	AB/AE (Alumina Oxide blasted / Acid Etched
Basic design	Spiral, slightly tapered 1° to 4° degree of taper, triple-lead thread	Spiral, straight-walled and slightly tapered, double-lead thread
Implant-abutment connection	Internal hex	Internal hex
Diameters (mm)	3.7, 4.1, 4.7, 6.0	3.3, 3.75, 4.2, 5.0, 6.0
Lengths (mm)	10, 11.5, 13, 16	3.3mmD - 10, 11.5, 13, 16, 18 3.75mmD - 8, 10, 11.5, 13, 16, 18 4.2mmD - 6.25, 8, 10, 11.5, 13, 16, 18 5.0mmD - 6.25, 8, 10, 11.5, 13, 16 6.0mmD - 6.25, 8, 10, 11.5, 13
Sterility	Sterile using gamma radiation	Sterile using gamma radiation
Prosthetic components	Healing abutments Cement-retained abutments (straight and angulated: 17°, 20°) Screw-retained abutments (straight and angular: 15°, 30°) Overdenture restorations (straight)	Healing abutments Cement-retained abutments (straight and angulated: 15°, 25°, 35°) Screw-retained abutments (straight and angulated: 17°, 30°, 45°) Overdenture restorations (straight) CAD/CAM components (Ti Bases, Ti Pre-Milled Abutment Blanks)
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #4 – EH MONO Implant by ETGAR Medical Implant Systems	Adin's One™ One-Piece Dental Implants
Intended use	The EH MONO one-piece implant and abutment is specially tailored for narrow alveolar ridges and is ideal for maxillary lateral and mandibular incisors.	Adin's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. Narrow implants identified as One™ One-piece dental implant in diameter of 3.0mm are indicated for use only in replacement of maxillary lateral incisors and mandibular lateral and central incisors.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Surface treatment	sandblasting followed by acid etching surface treatment	AB/AE (Alumina Oxide blasted/Acid Etched
Basic design	Integrated abutment post. Threaded with double-lead thread	Integrated abutment post. Threaded with double-lead thread
Implant-abutment connection	N/A (Monoblock implant)	N/A (Monoblock implant)

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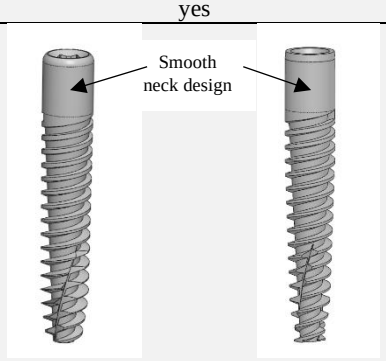
Product / Feature	Similar Device #4 – EH MONO Implant by ETGAR Medical Implant Systems	Adin's One™ One-Piece Dental Implants
Diameters (mm)	2.8, 3.3, 3.6, 4.2	3.0, 3.3, 3.6, 4.2, 5.0
Lengths (mm)	10, 11.5, 13, 15	10, 11.5, 13, 15
Sterility	Sterile using gamma radiation	Sterile using gamma radiation
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #5 – PteryFit by Norris Medical	Long Touareg CloseFit WP, Touareg UniFit & Touareg OS Implants
Intended use	Norris Dental Devices' implants are intended for surgical placement in the posterior region of the atrophic Maxilla and located in the Pterygomaxillary region to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.	Adin's dental implants are intended for surgical placement in the maxillary and/or mandibular arches to support single- or multiple-unit prosthetic restorations including cement-retained, screw-retained or overdenture restorations in partially or fully edentulous patients. Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Surface treatment	RBM treatment to roughen the implant surface blasting with Hydroxyapetite for surface roughening and enhanced osseointegration.	OsseoFix™ (calcium phosphate blasting)
Basic design	Spiral, tapered with double threads. designed to match the anatomy of the bone structure- the implant is composed of 3 parts; The lower V-shaped thread zone enables self-tapping. The middle zone square type thread is used for compressing cancellous bone and help achieving maximum BIC. The smooth "Neck" surface at the top helps in eliminating the adherence of Perio-Pathogens, thus reducing the chances of an inflammatory process to develop around the neck area.	Spiral, tapered, double-lead thread. Smooth 'neck-collar' is 5 mm smooth in either bone level or up to 5mm above bone level.
Implant-abutment connection	Internal hex connection	Internal hex in Touareg™-OS, Conical hex in Touareg CloseFit™ WP implants, Conical star in Touareg UniFit implants.
Diameters (mm)	4.2	4.2 – Touareg OS 4.3 – Touareg CloseFit™ and Touareg UniFit
Lengths (mm)	20, 22, 25 (for 4.2mmD)	Touareg™-OS: 20, 22.5, 25 (for 4.2mmD) Touareg CloseFit™: 20, 22.5, 25 (for 4.3mmD) Touareg UniFit: 20, 22.5, 25 (for 4.3mmD)
Sterility	Sterile using gamma radiation	Sterile using gamma radiation
CE-Marked	Yes	yes
Illustrations		 Touareg CloseFit WP (long) Touareg OS (long)

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Product / Feature	Similar Device #5 – PteryFit by Norris Medical	Long Touareg CloseFit WP, Touareg UniFit & Touareg OS Implants
Product / Feature	**Similar Device #6 –Straight Abutment by MIS Implants Technologies**	**Adin's RS Straight Titanium Abutment**
Intended use	Dental abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacement to restore chewing function.	Dental abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacement to restore chewing function.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Basic design	Cylindric shaped with conical hex connection	Cylindric shaped with conical hex connection
Diameters (mm)	4-5.5	1-5
Lengths (mm)	10	10.5-14.30
Sterility	Non-Sterile. Cleaning and sterilization as recommended in the IFU	Non-Sterile. Cleaning and sterilization as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #7 – Multi Unit Abutment Xeal by Nobel BioCare	Adin's Trans Mucosal Abutment
Intended use	Multi-Unit abutment in combination with endosseous implants are indicated for multiple unit reconstruction when screw retained prosthetics is preferred.	Adin's dental abutments are intended for use in conjunction with an endosseous dental implant fixture to aid in prosthetic rehabilitation, to support single and multiple tooth prosthesis in the mandible or maxilla.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Basic design	Have external Hex design at one side to engage with corresponding dental implant, and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.	Have external Hex design at one side to engage with corresponding dental implant, and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.
Angles	Straight, 17°, 30°	Straight, 17°, 30°, 45°
Lengths (mm)	Straight: 1.5, 4.5 17°: 2.5, 3.5 30°: 3.5, 5	Straight: 1, 2, 3, 4, 5 17°: 3, 4 30°: 3.5, 5
Sterility (mm)	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.
CE-Marked	Yes	Yes
Illustrations	 Angled Straight	 Angled Straight

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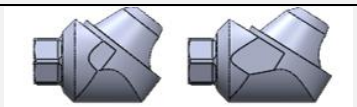
Product / Feature	Similar Device #8 – Multi Unit Abutment by Noris	Adin's Trans Mucosal Abutment
Intended use	The Multi-Unit system provides a solution for screw-retained prostheses even on complicated-to-restore implants (for example, multiple tilted implants). The Multi-Unit system comprises a full range of sizes for both the upper and lower jaws. Straight, 17°, 30°, 45°, 52° and 60° adaptors, in a variety of heights, connects to a wide range of complementary products.	Adin's 52° and 60° TMA with dental implants are intended for surgical placement in the maxillary arch to support splinted screw-retain bridges in edentulous or partially edentulous patients. Adin's 52° and 60° TMA may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Basic design	Have external Hex design at one side to engage with corresponding dental implant and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.	Have external Hex design at one side to engage with corresponding dental implant, and a cone design at the other side for engaging with temporary abutments or restorations. Have variation in cone angle to compensate different implant insertion directions.
Angles	Straight, 52°, 60°	Straight, 52°, 60°
Height (mm)	52°, 60°: 2 mm	52°, 60°: 5 mm
Sterility	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.	provided non-sterile and must be cleaned and sterilized prior to use, according to cleaning and sterilization instruction in the IFU.
CE-Marked	Yes	Yes
Illustrations	 52° 60°	 52° 60°

Product / Feature	Similar Device #9 – Titanium Base 2nd Generation by Medentika®	Adin's CloseFit™ Ti Base Engaged
Intended use	For the production of individual titanium/ceramic abutments (Hybrid abutments) on implants. Titanium/ceramic abutments consist of a titanium support the so-called titanium base 2nd Generation and a unique zirconia abutment. The individual titanium/ceramic abutments in combination with crowns and superstructures, for reconstruction of function and aesthetics be made.	Titanium base is intended for fabricating custom CAD/CAM abutments for single and multi-unit prostheses. (Abutment or directly bolted crown).
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti 6Al-4V ELI)	Titanium alloy (Ti 6Al-4V ELI)
Basic design	Have external Hex design or cylindrical shape at one side, for anti-rotation or free rotation, respectively. At the other side is cylindrical shaped for engaging with the final restoration. Fixed to corresponding implant through a prosthetic screw	Have external Hex design or cylindrical shape at one side, for anti-rotation or free rotation, respectively. At the other side is cylindrical shaped for engaging with the final restoration. Fixed to corresponding implant through a prosthetic screw
Diameters (mm)	3.5, 4.5, 5.7	2.75, 3.0, 3.5, 4.3, 5.0
Sterility	Titanium Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	Titanium Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

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Product / Feature	Similar Device #10 – Pre-face Abutment Blank by Medentika®	Adin's CloseFit™ Ti Pre Milled MDTK Abutment Blank
Intended use	For the production of individual titanium/CoCr abutments on implants (using CAD/CAM milling machines). The individual titanium/CoCr abutments can be produced in combination with crowns and bridges for the restoration of function and esthetics.	Adin CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple unit prostheses in the maxilla or mandible of a partially or fully edentulous patient.
Intended patient population	Partially or fully edentulous patient	Partially or fully edentulous patient
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Basic design	Titanium cylindrical shape with external Hex connection at on side to fit different implant platform. The cylinder/post intended to be milled to create customized abutment.	Titanium cylindrical shape with external Hex connection at on side to fit different implant platform. The cylinder/post intended to be milled to create customized abutment.
Diameters (mm)	11.5, 16.0	11.5, 15.8
Sterility	The Ti Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU	The Ti Base abutments are provided non-sterile, and comes with Cleaning and sterilization instructions as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #11 –Ball Attachment by MIS Technologies	Adin's Ball Attachment
Intended use	The ball attachment superstructure is intended to secure a removable prosthesis.	The ball attachment superstructure is intended to secure a removable prosthesis.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy + Titanium nitride coating	Titanium alloy (Ti-6Al-4V ELI) + Anodize
Basic design	Upper domain is ball shaped; lower domain connected to the implant has a threaded shape	Upper domain is ball shaped; lower domain connected to the implant has a threaded shape
Diameters (mm)	4-5	2.59-5
Lengths (mm)	1, 2, 3, 4, 5	0.5, 1, 2, 3, 4
Sterility	Non-Sterile, Cleaning and sterilization as recommended in the IFU	Non-Sterile, Cleaning and sterilization as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #12 –Temporary Abutment by Nobel BioCare	Adin's RS Temporary Abutment
Intended use	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Basic design	Cylindric shaped with internal hex connection	Cylindric shaped with internal hex connection. External features for cement retention
Diameters (mm)	4 – 5.5	2.30-4.5
Lengths (mm)	12	11.5
Sterility	Non-Sterile, Cleaning and sterilization as recommended in the IFU	Non-Sterile, Cleaning and sterilization as recommended in the IFU
CE-Marked	Yes	Yes

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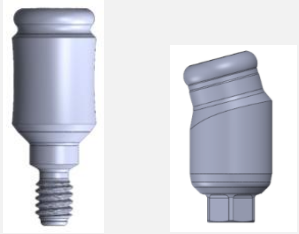
Product / Feature	Similar Device #12 –Temporary Abutment by Nobel BioCare	Adin's RS Temporary Abutment
Illustrations		

Product / Feature	Similar Device #13 – P4S-15 Anatomic angular abutment 15˚ with shoulder by AB Dental	Adin's RS Angled Titanium Abutment
Intended use	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.	Temporary dental abutments are intended to be used as temporary component to an endosseous implant to allow healing of the soft tissue.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium alloy (Ti-6Al-4V ELI)	Titanium alloy (Ti-6Al-4V ELI)
Basic design	Cylindric 15˚ tilted shape	Cylindric 15˚ tilted shape
Diameters (mm)	4	4.7
Lengths (mm)	1, 2, 3	1, 2, 3
Sterility	Non-Sterile, Cleaning and sterilization as recommended in the IFU	Non-Sterile, Cleaning and sterilization as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

Product / Feature	Similar Device #14 – NOVALOC® abutments by Straumann	Adin's Grip abutments
Intended use	The Novaloc® Abutments are designed to be used with the Thommen Medical dental implant lines SPI®ELEMENT and SPI®CONTACT, to retain overdentures or partial overdentures.	Grip abutments are intended to be used in conjunction with endosseous dental implants to aid in prosthetic rehabilitation in partially or completely edentulous patients.
Intended patient population	Partially or fully edentulous patients	Partially or fully edentulous patients
Materials	Titanium Grade 5/ADLC	Titanium alloy (Ti-6Al-4V ELI)
Basic design	Straight or angulated (15˚) shape	Straight or angulated (15˚) shape
Diameters (mm)	3.87	3.87
Lengths (mm)	1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 6.5, 7.5	2, 3, 4, 5, 6
Sterility	Non-Sterile, Cleaning and sterilization as recommended in the IFU	Non-Sterile, Cleaning and sterilization as recommended in the IFU
CE-Marked	Yes	Yes
Illustrations		

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Appendix C - List of Applied Standards and Common Specifications

Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
General				
EN ISO	13485	Quality Systems – Medical Devices –System requirements for regulatory purposes	2016 + A11:2021	Fully, except for service provision and customer property (not applicable for Adin's QMS).
EN ISO	14971	Medical devices – Application of risk management to medical device	2019-A11:2021	Fully, per FMEA method.
EN ISO	10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process;	2020	Fully, except for non-applicable tests based on device category and risk management process.
EN	62366-1	Medical devices - Application of usability engineering to medical devices	2015 + A1:2020	Fully
EN ISO	20417	Medical devices — Information to be supplied by the manufacturer	2021	Fully
EN ISO	15223-1	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	2021	Fully
ISO	14801	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants	2016	Fully
ASTM	F2503	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	2020	Fully
Materials				
ASTM	F136-13	Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (extra low interstitial) alloy for surgical implant applications	2021	Fully
EN ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2021	Fully
ASTM	F1537-20	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2020	Fully
ISO	5832-12	Implants for surgery – Metallic materials – Part 12: Wrought cobalt-chromium-molybdenum alloy	2019	Fully
Sterile Devices				
EN	556-1	Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2001	Fully
EN ISO	11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2015 + A2:2019	Fully
EN ISO	11137-2	Sterilization of health care products- radiation – Part 2: Establishing the sterilization dose	2015	Fully, in conjunction with ISO/TS 13004:2013
EN ISO	11137-3	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	2017	Fully
ISO/TS	13004	Sterilization of health care products –Radiation – Substantiation of selected sterilization dose: Method VDmaxSD	2013	Fully in conjunction with EN ISO 11137-2:2015
EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020	Fully, per applicable selected tests for rigid microbial barrier package (tube).

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Standard Source	Standard Number	Standard Name	Recent Revision	Level of compliance (fully or partially)
EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020	Full compliance with selected tests.
EN ISO	11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2018 + A1:2021	Fully
EN ISO	11737-2	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2020	Fully
Non-sterile devices				
EN ISO	17665-1	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2006	Fully
ISO/TS	17665-2	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1	2009	Fully
EN ISO	17664-1	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices	2021	Fully
AAMI	TIR12	Designing, Testing, And Labeling Medical Devices Intended for Processing by Health Care Facilities: A Guide for Device Manufacturers	2020	Fully
Manufacture / processes				
EN ISO	14644-1	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration	2015	Fully. For ISO class 7
EN ISO	14644-2	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	2015	Fully
EN ISO	14644-3	Cleanrooms and associated controlled environments – Part 3: Test methods	2019	Fully
EN ISO	14644-4	Cleanrooms and associated controlled environments – Part 4: Design, construction and start-up	2001	Fully
EN ISO	14644-5	Cleanrooms and associated controlled environments – Part 5: Operations	2004	Fully
ISO	2859-1	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	1999 (AMD 1:2011)	Fully

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Appendix D – Literature Review Bibliography

Below are the sources used for the literature review conducted to identify publications through a search of the scientific literature pertaining to the performance and safety of Adin's dental implants and abutments:

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- T. Grandi, L. Svezia and G. Grandi , "Narrow implants (2.75 and 3.25 mm diameter) supporting a fixed splinted prostheses in posterior regions of mandible: one-year results from a prospective cohort study," International Journal of Implant Dentistry, vol. 3, pp. 1-7, 2017.
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- P. Maló, M. de Araújo Nobre, A. Lopes and R. Rodrigues, "Preliminary report on the outcome of tilted implants with longer lengths (20-25 mm) in low-density bone: oneyear follow-up of a prospective cohort study," Clinical Implant Dentistry and Related Research, vol. 17, no. S1, pp. e134-e142, 4 September 2013.
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- L.-E. M. J. P. J.-I. S. Helena Alsterstål-Englund, "A retrospective clinical evaluation of extensive tooth-supported fixed dental prostheses after 10 years," The Journal of Prosthetic Dentistry, vol. 125, no. 1, pp. 65-72, 2021.
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- D. T. L. L. Michael Klein, "Marginal Bone Changes on Ultraclean, Micro-Threaded Platform-Switched Implants Following Restoration: 1- to 4-Year Data," Compend Contin Educ Dent., vol. 41, no. 4, pp. e7-e18, 2020.
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- K. I. K.-i. M. Y. M. Sayaka Tada, "Multifactorial risk assessment for survival of abutments of removable partial dentures based on practice-based longitudinal study," Journal of Dentistry, vol. 41, no. 12, pp. 1175-1180, 2013.
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- A. E. B. S. S. E. G. D. L. F. C. F. Grecchi, "A new surgical and technical approach in zygomatic implantology," Oral Implantol (Rome), vol. 10, no. 2, p. 197–208, 27 September 2017.CER-IMP Rev.11 Page 113 of 114
- N. Hamudi, E. Barnea, E. Weinberg, A. Laviv, E. Mijiritsky, S. Matalon, L. Chaushu and R. Kolerman, "The Association of the One-Abutment at One-Time Concept with Marginal Bone Loss around the SLA and Platform Switch and Conical Abutment Implants," Journal of Clinical Medicine, vol. 11, no. 1, pp. 1-18, 2021.

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