October 17, 2025

Adin Dental Implant Systems Ltd.
% Floyd Larson
President
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K250178
Trade/Device Name: Adin Customized Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: January 21, 2025
Received: September 22, 2025

Dear Floyd Larson:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K250178

Device Name

Adin Customized Abutments

Indications for Use *(Describe)*

Adin Customized Abutments are intended for use with Adin dental implants in partially or fully edentulous mandibles and maxillae, as a support for single-unit or multiple-unit screw-retained or cement-retained restorations.

All digitally designed abutments for use with Adin Ti-base and Adin Ti-blanks are intended to be sent to an FDA-registered Adin Dental Implants validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: scans from desktop and intraoral scanners, CAD and CAM software and a milling machine with associated accessories.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Adin Dental Implant Systems Ltd
Adin Customized Abutments

October 16, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Adin Dental Implant Systems Ltd. Alon Tavor Industrial Zone P.O.B. 1128 Afula 1811101, Israel Telephone: +972-4-6426-732
Official Contact	Dimitry Beliavsky, RA Specialist
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Adin Customized Abutments
Common Names	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Secondary Product Code	PNP
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (OHT 1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B, Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K221301, DESS Dental Smart Solutions, Terrats Medical SL.

Reference Devices
K223714, UniFit Dental Implant System, Adin Dental Implant Systems Ltd.
K112585, Touareg CloseFit Dental Implant System, Adin Dental Implant Systems Ltd.
K081751, Adin Dental Implants System, Adin Dental Implant Systems Ltd.

K223677, Titanium Abutment Blank Nobel Biocare N1™ TCC, Nobel Biocare AB
K153111, Touareg CloseFit UNP 2.75mmD, Adin Dental Implant Systems Ltd.
K140293, Touareg NP CloseFit Dental Implants System, Adin Dental Implant Systems Ltd.

INDICATIONS FOR USE STATEMENT

Adin Customized Abutments are intended for use with Adin dental implants in partially or fully edentulous mandibles and maxillae, as a support for single-unit or multiple-unit screw-retained or cement-retained restorations.

All digitally designed abutments for use with Adin Ti-base and Adin Ti-blanks are intended to be sent to an FDA-registered Adin Dental Implants validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: scans from desktop and intraoral scanners, CAD and CAM software and a milling machine with associated accessories.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for Adin Customized Abutments, a series of components compatible with dental implants from Adin Dental Implant Systems Ltd., intended for use in the fabrication of patient-specific abutments. The subject device components include CAD CAM abutments (Ti-bases, Ti-blanks). All patient-specific abutment fabrication is by prescription on the order of the clinician. Fabrication of patient-specific abutments will be performed at validated milling centers or, by using a validated digital dentistry workflow, at point-of-care facilities..

The design and fabrication of the zirconia superstructure for Ti-bases or of patient-specific abutments from Ti-blanks will be conducted using a digital dentistry workflow requiring the use of the following equipment and software:

Scanner:	iTero Intra Oral Scanner or Medi Corp. Identica 3D Desktop scanner
Design Software:	EXOCAD AbutmentCAD design software (K193352)
CAM Software:	WORKNC Dental
Milling Machine:	Ceramill Motion 2.

The superstructures to be used on Ti-bases are to be made from the following material and are to be cemented as follows:

Zirconia Material:	ArgenZ Ultra (K071410)
Cement:	PANAVIA V5 (K150704).

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 Instructions for Use (IfU) accompanying the device.

No compatibility with implants other than those from Adin Dental Implant Systems Ltd. is claimed or intended. Ti-bases are compatible with Adin Dental implants cleared in K081751 and K223714. Ti-blanks are compatible with Adin Dental implants cleared in K081751, K153111, K140293, and K112585.

Ti-base abutments are two-piece abutments, with the base component cemented to a CAD CAM fabricated zirconia superstructure. The final two-piece abutment (base and cemented superstructure) is the finished device used for the prosthetic restoration. Each patient-specific superstructure is individually prescribed by the clinician.

Ti-base abutments are provided with a compatible abutment screw that retains the base to the implant (the restoration is screw-retained on the implant level). The manufactured superstructure is attached to the Ti-base.

Engaged Ti-bases include anti-rotational connections that engage with the dental implant and are intended for single tooth restorations. Non-engaged Ti-bases include round connections that do not limit rotation and are intended for multi-unit/bridge restorations. Ti-base Angular are provided only in engaging designs.

The all-metal Ti-base components are straight with regard to the implant axis. Angular Ti-base includes an angled upper portion that allows the screw channel either to be straight relative to the implant axis or to be angled to allow for moving the screw channel in an oral direction (up to 20°) for esthetic purposes.

All Ti-bases are color coded per platform by an anodizing process for easier identification. Adin Ti-bases are available for Adin implant platform connections (standard internal hex – RS, and UniFit - UF)

The all-metal Ti-base components are provided in engaging and non-engaging versions with gingival heights ranging from 0.65 mm to 4.0 mm. They are provided with post heights of 4.0, 6.0, and 8.0 mm. Ti-base Angular is a component with gingival heights ranging from 1.0 mm to 3.0 mm, provided in an engaging design. Ti-base Angular includes an angular cutout in the post to allow for moving the screw channel in an oral direction for esthetic purposes. It is provided with post heights from 4.0 mm to 8.0 mm.

The design parameters for the CAD CAM zirconia superstructure to be used on Ti-base and Ti-base Angular, are:

Minimum wall thickness – 0.5 mm
Minimum post height for single unit restorations – 4.0 mm
Minimum gingival height – 0.0 mm
Maximum gingival height – 4.5 mm
Maximum angulation of the final abutment - 20°

Adin Ti-blank abutments include on one side a pre-fabricated connection for the dental implant and on the other side a pre-fabricated connection to the milling machine blank holder. They are available in diameters of 11.5 mm and 15.8 mm and are provided with a compatible abutment screw.

All Ti-blank designs are subject devices to be manufactured using a CAD CAM workflow. Ti-blank abutments are provided in engaging and non-engaging designs, are available for all Adin implant platform connections, and are made of titanium alloy (Ti 6Al 4V).

The design parameters for Ti-blanks are:

Minimum wall thickness – 0.7 mm for RS; 0.5 mm for UNP, NP, RP, WP
Minimum post height for single unit restorations – 4.0 mm
Maximum milled abutment height above implant level – 10 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 4.0 mm for RS; 1.0 mm for UNP; 3.0 mm for NP, RP, WP
Maximum angulation of the final abutment – 25° for RS, NP, RP, WP; 15° for UNP

PERFORMANCE DATA

Non-clinical data provided in this submission in support of substantial equivalence included:

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, “Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices,” Journal of Testing and Evaluation Volume 49, No. 2 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition; the rationale addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, including magnetically induced displacement force and torque;;

- referenced from K223714 was moist heat sterilization validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to ISO 17665-1 and ISO 17665-2;
- confirmatory biocompatibility testing referenced from K223714 for titanium alloy conforming to ASTM F136 and superstructure made from from Argen Z Ultra zirconia, attached with Panavia V5 cement;
- confirmatory biocompatibility testing performed according to ISO 10993-5, Annex C (MTT), for patient-specific abutments manufactured from subject device Ti-blanks according to the validated digital dentistry workflow;
- mechanical testing conducted according to ISO 14801
- validation of CAD software to demonstrate that the maximum and minimum design parameters for the subject devices are locked into the design software and available libraries;
- validation of CAM software and the milling machine to ensure protection of the implant-abutment connection, the accuracy and reliability of the milling process, file imports, milling tools, materials, milling strategies and post-processing procedures.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

The primary predicate device K221301 is in support of substantial equivalence of the Indications for Use, digital dentistry workflow, and abutment designs. Reference device K223714 is in support of substantial equivalence of abutment designs, materials, manufacturing, sterilization and biocompatibility. Reference device K112585 is in support of substantial equivalence of abutment designs and the conical/hex implant/abutment platform connection. Reference Device K081751 is in support of substantial equivalence of abutment designs, the RS internal hex connection and bridge abutments' diameters of 3.9-4.5 mm. Primary predicate device K221301 and reference device K223677 are in support of substantial equivalence of the digital dentistry workflow for Ti-blanks and Ti-bases. Ti-bases are compatible with Adin Dental implants cleared in K081751 and K223714. Ti-blanks are compatible with Adin Dental implants cleared in K081751, K153111, K140293, and K112585.

The Indications for Use Statement (IFUS) for the subject device is similar to relevant portions of the IFUS for the primary predicate device K221301 and the reference devices. The Indications for Use Statements for reference devices K223714, K112585 and K081751 include language for dental implants that is not applicable to the subject device.

The IFUS for the subject device is similar to that of the primary predicate device K221301. The IFUS of this predicate device refers to use in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. The table of compatible implants in the IFUS for primary predicate device K221301 is not relevant to the subject device because the subject device is compatible only with implants manufactured by Adin Dental Implant Systems Ltd. No compatibility with third-party implants is claimed.

Substantial equivalence of the subject device Ti-bases is supported by the primary predicate device K221301 and by reference devices K223714, K112585, and K081751. The titanium components of subject device Ti-bases are identical to those from the Adin Dental reference devices, except for the use of a digital dentistry workflow for manufacture of the superstructure under FDA Product Code PNP. The latter is supported by the primary predicate device K221301.

Subject device Ti-blanks are supported by the primary predicate device K221301 and by reference devices K223714, K112585, K081751, and K223677.

Substantial equivalence of biocompatibility of the subject device titanium abutments and zirconia superstructure is supported by reference device K223714 and the fact that materials and processing of subject and reference devices are identical. Substantial equivalence of biocompatibility of patient-specific abutments manufactured from subject device Ti-blanks according to the validated digital dentistry workflow is supported by testing according to ISO 10993-1, ISO 10993-5 and ISO 10993-12.

The subject device abutments and abutment screws are provided non-sterile to the end user and are intended to be sterilized by the end-user by means of most heat (steam), as are the abutments and abutment screws of reference device K223714. All subject device components are packaged in a pouch made of polyethylene terephthalate (PET), biaxially oriented polypropylene (BOPP) and polyethylene (PE). This is the same packaging used for reference device K223714.

The risks associated with the subject device abutment designs are mitigated by mechanical testing and an engineering rationale provided in the attachment *Performance Testing – Bench.* The mechanical testing data and engineering rationale demonstrate that the subject device angled abutments in combination with the Adin Dental compatible implants have sufficient strength for their intended use.

Overall, the subject devices have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate the same or very similar materials, and
- have similar packaging and are sterilized using the same materials and processes.

The basis for the belief of Adin Dental Implant Systems, Ltd that the subject device is substantially equivalent to the predicate devices is summarized in the following Tables of Substantial Equivalence.

Table 1. Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device Adin Customized Abutments Adin Dental Implants Systems Ltd.	Adin Customized Abutments are intended for use with Adin dental implants in partially or fully edentulous mandibles and maxillae, as a support for single-unit or multiple-unit screw-retained or cement-retained restorations. All digitally designed abutments for use with Adin Ti-base and Adin Ti-blanks are intended to be sent to an FDA-registered Adin Dental Implants validated milling center for manufacture or to be manufactured according to the digital dentistry workflow, which integrates multiple components: scans from desktop and intraoral scanners, CAD and CAM software and a milling machine with associated accessories.
Primary Predicate Device K221301 DESS Dental Smart Solutions Terrats Medical SL	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. [Table of Compatible Implant Systems not shown, NA.]
Reference Device K223714 UniFit Dental Implant System Adin Dental Implants Systems Ltd.	UniFit Dental Implant System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges or overdentures in partially or completely edentulous patients in order to restore masticatory function. UniFit Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. UniFit short implants (6 mm L) are intended to be used only with straight abutments. All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to an Adin Dental validated milling center for manufacture.

	Indications for Use Statement
Reference Device K112585 Touareg CloseFit Dental Implant System Adin Dental Implant Systems Ltd.	Touareg CloseFit™ Dental 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. Touareg CloseFit™ Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
Reference Device K081751 Adin Dental Implants System Adin Dental Implant Systems Ltd.	Adin Dental 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. Adin Dental Implants may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.
Reference Device K223677 Titanium Abutment Blank Nobel Biocare N1™ TCC Nobel Biocare AB	Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic rehabilitation for single units and multiple units of up to three units. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Table 2. Table of Substantial Equivalence – Technological Characteristics – Ti-bases

Feature	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	Adin Customized Abutments **Adin Dental Implants Systems Ltd.**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K223714** **UniFit Dental Implant System** **Adin Dental Implants Systems Ltd.**	**K112585** **Touareg CloseFit Dental Implant System** **Adin Dental Implant Systems Ltd.**	**K081751** **Adin Dental Implants System** **Adin Dental Implant Systems Ltd.**
Product Code	NHA, PNP	NHA, PNP	NHA, DZE	NHA, DZE	NHA, DZE
Design					
Abutment Design	CAD/CAM Ti-base	CAD/CAM TiBase	CAD/CAM TiBase	CAD/CAM TiBase	CAD/CAM TiBase
Prosthesis Attachment	Cement-retained, Screw-retained	Cement-retained Screw-retained	Cement-retained, Screw-retained	Cement-retained, Screw-retained	Cement-retained, Screw-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit,	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/Implant Platform Diameter (mm)	4.5, 5.5	2.52-6.5	4.7-5.2	4.7-5.2	4.7-5.2
Abutment/ Implant Interface	Internal Hex, Internal Conical Star	Various	Internal Conical Star	Internal Conical Hex	Internal Hex
Gingival height of titanium component, mm	0.65-4	0.3-3	1-4	0.5-6	0.5-6
Superstructure minimum wall thickness, mm	0.5	0.4	0.5	0.4	0.4
Minimum cementable post height of superstructure for single unit restorations, mm	4.0	4.0	4.0	4.0	4.0

Feature	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	Adin Customized Abutments **Adin Dental Implants Systems Ltd.**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K223714** **UniFit Dental Implant System** **Adin Dental Implants Systems Ltd.**	**K112585** **Touareg CloseFit Dental Implant System** **Adin Dental Implant Systems Ltd.**	**K081751** **Adin Dental Implants System** **Adin Dental Implant Systems Ltd.**
Superstructure maximum gingival height, mm	4.5	6.0	4.5	4.5	4.5
Superstructure minimum gingival height, mm	0	0.5	0	0	0
Superstructure maximum angulation	20°	0° (Straight only)	20°	20°	20°
CAD/CAM System	Digital dentistry workflow, Validated Milling Center	Digital dentistry workflow, Validated Milling Center	Validated Milling Center	Validated Milling Center	Validated Milling Center
Material					
Titanium component	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Superstructure	Zirconia	Zirconia (VITA YZ ST and VITA YZ XT)	Zirconia	Zirconia	Zirconia
Cement recommended in labeling	Panavia V5	Ivoclar Vivadent Multi-Link	Panavia V5	Panavia V5	Panavia V5
Sterility	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user
Sterilization by end user	Moist heat	Moist heat	Moist heat	Moist heat	Moist heat

Table 3. Table of Substantial Equivalence – Technological Characteristics – Ti-blanks

Feature	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Adin Customized Abutments **Adin Dental Implants Systems Ltd.**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K223714** **UniFit Dental Implant System** **Adin Dental Implants Systems Ltd.**	**K112585** **Touareg CloseFit Dental Implant System** **Adin Dental Implant Systems Ltd.**	**K081751** **Adin Dental Implants System** **Adin Dental Implant Systems Ltd.**	**K223677** **Titanium Abutment Blank Nobel Biocare N1™ TCC** **Nobel Biocare AB**
Product Code	NHA, PNP	NHA, PNP	NHA, DZE	NHA, DZE	NHA, DZE	NHA, PNP
Design						
Abutment Design	CAD/CAM Ti Blank	CAD/CAM Ti Blank	CAD/CAM Ti Blank	CAD/CAM Ti Blank	CAD/CAM Ti Blank	CAD/CAM Ti Blank
Prosthesis Attachment	Cement-retained	Cement-retained	Cement-retained	Cement-retained	Cement-retained	Cement-retained
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/ Implant Interface	Internal Hex, Internal Conical Hex, Internal Conical Star	Various	Internal Conical Star	Internal Conical Hex	Internal Hex	Internal Trioval Conical Connection
Abutment/Implant Platform Diameter (mm)	2.3-3.4	2.3-6.0	2.9	2.3-3.4	2.5-3.4	3.21-3.49
Blank diameter, (mm)	11.5, 15.8	10, 14	11.5, 15.8	11.5, 15.8	11.5, 15.8	10
Minimum wall thickness, (mm)	0.7 for RS; 0.5 for UNP, NP, RP, WP	0.45	0.5	0.5	0.5	0.38
Minimum gingival height, (mm)	0.5	0.3	0.5	0.5	0.5	0.335
Maximum gingival height, (mm)	4.0 mm for RS, 1.0 for UNP; 3.0 for NP, RP, WP	6.0	6.0	6.0	6.0	4.6

Feature	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Adin Customized Abutments **Adin Dental Implants Systems Ltd.**	**K221301** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K223714** **UniFit Dental Implant System** **Adin Dental Implants Systems Ltd.**	**K112585** **Touareg CloseFit Dental Implant System** **Adin Dental Implant Systems Ltd.**	**K081751** **Adin Dental Implants System** **Adin Dental Implant Systems Ltd.**	**K223677** **Titanium Abutment Blank Nobel Biocare N1™ TCC** **Nobel Biocare AB**
Minimum cementable post height for single unit restorations, (mm)	4.0	4.0	4.0	4.0	4.0	4.05
Maximum milled abutment height, (mm)	10	19	10	10	10	16
Maximum angulation	25° for RS, NP, RP, WP; 15° for UNP	30°	20°	20°	20°	30°
CAD/CAM System	Digital dentistry workflow, Validated Milling Center	Digital dentistry workflow, Validated Milling Center	Validated Milling Center	Validated Milling Center	Validated Milling Center	Digital dentistry workflow, Validated Milling Center
Abutment Material	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI	Ti-6AI-4V ELI
Sterility	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user
Sterilization by end user	Moist heat	Moist heat	Moist heat	Moist heat	Moist heat	Moist heat