December 29, 2023

Adin Dental Implant Systems Ltd.
Kevin Thomas
Vice President and Director of Regulatory Affairs
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K223714
Trade/Device Name: UniFit Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 30, 2023
Received: December 1, 2023

Dear Kevin Thomas:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223714

Device Name

UniFit Dental Implant System

Indications for Use *(Describe)*

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.

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 UNIFIT DENTAL IMPLANT SYSTEM
K223714

DATE PREPARED: December 23, 2023

1. ADMINISTRATIVE INFORMATION

510(K) OWNER NAME

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Kevin A. Thomas, Ph.D., VP, Dir Reg Affairs
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2. DEVICE NAME

Common/Usual Name: UniFit Dental Implant System
Proprietary/Trade name: UniFit Dental Implant System
Classification: Adin UniFit Dental Implant System has been classified as **Class II** devices under the following classification names:

Classification Name#	Product Code	21 CFR Ref.	Panel
Endosseous dental implant	DZE (Primary)	872.3640	Dental
Endosseous dental implant abutment	NHA (Secondary)	872.3630	

3. PREDICATE AND REFERENCE DEVICES

Adin's UniFit Dental Implant System is substantially equivalent to the following Predicate and Reference Devices:

3.1 Primary predicate device: Adin's Touareg™ CloseFit Dental Implant System, cleared under 510(k) number K112585 on May 24, 2012.

3.2 Reference device (for Ti Blank only): Imagine Milling Technologies, LLC's MIST IC abutments (PREFIT), cleared under 510(k) number K182246 on April 16, 2019.

3.3 Reference device Adin's Dental Implants System, cleared under 510(k) number K081751 on December 19, 2008.

3.4 Reference device: MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments, cleared under 510(k) number K172505 on December 27, 2017.

3.5 Reference device: MIS's Short Implants, cleared under 510(k) number K103089 on September 15, 2011.

3.6 Reference device: Straumann's BLX Implant System, cleared under 510(k) number K173961 on June 05, 2018.

3.7 Reference device: Adin's Touareg NP CloseFit™ Dental Implant System, cleared under 510(k) number K140293 on October 31, 2014.

3.8 Reference device: MIS CONNECT Superstructures (Cementing Caps), cleared under 510(k) number K173326 on March 16, 2018.

3.9 Reference device: Neobiotech Co., Ltd. IS Multi-Unit Abutment System (Multi-Unit Abutment Cylinder), cleared under 510(k) number K210903 on March 16, 2018.

3.10 Reference device: TruAbutment Inc., URIS OMNI Narrow System & Prosthetic (Multi-unit Base), cleared under 510(k) number K200817 on October 7, 2020.

3.11 Reference device: DESS Dental, Smart Solutions Terrats Medical SL, DESS Aurum Base, cleared under 510(k) number K212628 on March 11, 2022.

4. DEVICE DESCRIPTION

Adin's UniFit Dental Implant System is a new model that provides an additional connection platform to Adin's legally marketed Dental Implant Systems, indicated for use in surgical and restorative applications for placement in the maxillary and/or mandibular arch to provide support for prosthetic devices such as crowns, bridges, or overdentures in order to restore masticatory function.

This new UniFit model is identical to Adin's cleared *Touareg™ CloseFit* (RP- Regular Platform, and WP- Wide Platform) and Adin's *Touareg™-S* implant systems (cleared under K112585 and K081751, respectively) except for the "Star" (Torx) connection and new 6mm length for specific diameters.

The UniFit Dental Implant System includes dental implants, abutments, screws and prosthetic components for CAD/CAM restorations.

The UniFit dental implants are tapered core implants with a spiral tap, and a dome apex and double lead thread design.

- UniFit implants are available in the following diameters and lengths:

	Outer Diameter (mm)	Length (mm)
CloseFit Based	3.5	8, 10, 11.5, 13, 16, 18
	3.75	8, 10, 11.5, 13, 16, 18
	4.3, 5	6, 8, 10, 11.5, 13, 16, 18
Toureg-S Based	6	6, 8, 10, 11.5, 13

- The UniFit healing abutments are available in heights of 6.8-11.3mm, with diameters of 3.5-5.5mm and gingival heights of 2.0-6.0mm.
- The UniFit cement-retained and screw-retained abutments are available in diameters of 3.5-5.5mm, total heights of 10.20-18.20mm and angulations of 15°-30°.
- The UniFit UCLA Abutments are available in diameters 4.7-5.2mm.
- The UniFit Overdenture Attachments (ball attachment) are available in a diameter of 3.1mm and length of 9.3-13.8mm.
- The UniFit Implant Cover Screws are available in length of 5.0mm and outer diameters of 2.93mm.
- The UniFit Abutment Screws are available in length of 7.0-12.0mm and outer diameters of 2.2 and 3.1mm.
- Flat connection abutment's components:

- Flat Connection Gluing Ring is available with outer diameters of 4.5mm and total height of 3.8mm.

- Flat connection retaining screw available in length of 5.0mm and outer diameter of 2.5mm.

- The UniFit Prosthetic Components for CAD/CAM Restorations are available in the following dimensions:

  - Ti Blanks – outer diameters of 11.50mm and 15.80mm, total height of 24mm.

  - TMA Cementing Cone and Single TMA Cementing Cone – outer diameters of 4.30mm and 4.90mm, total height of 4.90mm.

  - Ti Bases – outer diameters of 4.5mm-6.5mm, lengths of 7.7mm-14.7mm, gingival heights of 1.2mm and 3.4 mm, and restoration height / post height of 4.0mm-8.0mm.

All UniFit implants have the OsseoFix™ Calcium Phosphate blast surface treatment, and all UniFit implants, abutments and respective screws are intended for single use only.

UniFit implants and abutments are made of 6Al-4V-ELI Titanium alloy complying with ASTM F136-13(2021)e1 (Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications) and ISO 5832-3:2021 (Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy).

The submission also includes two-piece abutments, with a titanium base as a pre-manufactured abutment used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment). The zirconia material is Argen Z Ultra, cleared in K071410, and the cement is Panavia V5, cleared in K150704.

All body contact materials of the UniFit Dental Implant System were evaluated for biocompatibility in accordance with ISO 10993-1, ISO 7405 and FDA guidance for Use of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", dated September 4, 2020.

5. INDICATIONS FOR USE

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.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Adin's UniFit Dental Implant System has the same intended use as Primary predicate Adin Touareg CloseFit™ cleared under K112585 and Reference devices Adin Dental Implant System cleared under K081751, MIS's MIS C1 Narrow Platform Conical Connection Implant System MIS C1 Wide Platform Conical Connection Abutments cleared under K172505, MIS's MIS Short Implants cleared under K103089, and Strauman's BLX Implant System cleared under K173961.

All UniFit implants have the OsseoFix™ Calcium Phosphate blast surface treatment, also used for Primary predicate Adin Touareg CloseFit™ cleared under 510(k) K112585.
For the purpose of substantial equivalency, UniFit Dental Implant System is supported by Primary predicate Adin Touareg CloseFit™ cleared under K112585, and further supported by Reference devices K081751 and K103089 to cover the length and Outer Diameter (OD) dimensions, and by Reference devices K172505 and K173971 to cover the conical "Star" (Torx) shaped connection.

The subject device and its Predicate and Reference devices have the same technology and basic performance characteristics. Adin's Touareg CloseFit™ implant external design (RP and WP platforms, Primary predicate K112585) is identical to the subject device for almost all dimensions (OD and length). The length dimensions' differences were bridged by Reference devices Adin Touareg™-S Implant System (K081751 and MIS short implants (K103089).

The subject and Predicate and Reference devices are manufactured from the same biocompatible Titanium alloy and undergo same machining, surface treatment and sterilization processes.

It was therefore concluded that Adin's UniFit Dental Implant System is substantially equivalent to the Predicate and Reference devices.

Furthermore, Adin UniFit Dental Implant System abutments share the same material, connection type, dimensions and angulation as the Primary predicate Adin Touareg CloseFit™ Dental Implant System (K112585) and Reference devices Adin Dental Implants System, cleared under K081751, Straumann's BLX Implant System, cleared under K173961, MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments, cleared under K172505, and Adin's Touareg NP CloseFit™ Dental Implant System, cleared under K140293.

Adin UniFit Dental Implant System Ball Attachments share the same material as the Primary predicate device Adin Touareg CloseFit™ Dental Implant System (K112585). The connection is identical to the Reference device MIS C1 Wide Platform Conical Connection Abutments (K172505). The dimensions are within the range of the Primary predicate, K112585, and Reference device, K172505. The angulation is identical to that of the Primary predicate, K112585, and similar to that of the Reference device, K172505.

Adin UniFit Dental Implant System TMA and STMA Cementing Cones are substantially equivalent to the Reference devices selected by Adin. For TMA and STMA Cementing Cones, Adin has identified the following three 510(k) cleared reference devices: MIS CONNECT Superstructures (Cementing Caps), cleared under K173326, Neobiotech Co., Ltd., IS Multi-Unit Abutment System (Multi-Unit Abutment Cylinder), cleared under K210903, and TruAbutment Inc., URIS OMNI Narrow System & Prosthetic (Multi-unit Base), cleared under K200817.

Adin UniFit Dental Implant System Ti Bases are substantially equivalent to the Reference devices selected by Adin. For Ti Bases, Adin has identified the following two 510(k) cleared Reference devices: DESS Dental Smart Solutions Terrats Medical SL, DESS Aurum Base, cleared under K212628, and previously mentioned MIS C1 Wide Platform Conical Connection Abutments, cleared under K172505.

Adin UniFit Dental Implant System Ti Blanks are substantially equivalent to the Primary Predicate device and Reference devices selected by Adin. For Ti Blanks, Adin has identified the 510(k) cleared Imagine Milling Technologies, LLC's MIST IC abutments (PREFIT), cleared under K182246 as a Reference device as well as two other 510(k) cleared products as Reference devices. The devices that are substantially equivalent to Adin UniFit Ti Blanks are the previously mentioned two devices, DESS Dental Smart Solutions Terrats Medical SL,

DESS Aurum Base (K212628), and MIS C1 Wide Platform Conical Connection Abutments (K172505).

7. PERFORMANCE DATA

A series of safety and performance tests and evaluations were performed to demonstrate that Adin's UniFit Dental Implant System is substantially equivalent to the Predicate and Reference devices. These tests and evaluations included:

1) **UniFit connection design effectiveness test (including system assembly) –** The purpose of this test is to verify the effectiveness of the UniFit implant-abutment connection design and assembly in accordance with the tolerance analysis performed during design phase. UniFit assemblies (implant, abutment and abutment screw) were tested together, in accordance with Adin internal protocol under predefined applied tightening torque, as expected in the clinical use. All tested specimens showed stable connection and all measurements were found to be within each component's specification.
2) **UniFit implant connection performance test – maximal applicable torque resistance –** The purpose of this test is to verify that the UniFit implants' internal connection, withstands the maximal insertion torque as predefined in the implants' specification, considering safety margins and device design). This test was conducted in accordance with Adin internal protocol.
3) **UniFit tool to implant connection life time performance –** The purpose of this test is to verify the interaction between the UniFit implant and its designated insertion reusable tool. The test was conducted at the end of the reusable tool's recommended lifetime. During this test, the maximal applied torque and deformation test met the predefined acceptance criteria and no mechanical or visual damages were observed. The test was conducted in accordance with Adin internal protocol.
4) **UniFit Implant-abutment connection analysis - degree of rotation –** The purpose of this test is to verify UniFit implant-abutment connection degree of free rotation after applying closure torque. All tested specimens met the predefined acceptance criterion. The test was conducted in accordance with Adin internal protocol.
5) **UniFit abutment screw performance test - maximum applicable torque –** The purpose of this test is to verify the torque resistance of the connecting screw and to verify that once breakage occurs, the break location is under the screw head (groove). The test was conducted by insertion of the abutment and the abutment screw into a fixated implant and to apply torque until the screw fails (breaks). All the tested screws failed in values above the

acceptance criteria and at the desired location (weak-point). The test was conducted in accordance with Adin internal protocol.

6) **UniFit screw loosening and abutment extraction by retrieval tool test –** The purpose of this test is to verify the ability to screw and loosen the screw with no deformation or fracture and to release the abutment after connection under lateral pressure. The test verified that UniFit screw retrieval torque withstands the predefined torque per its specification requirements. It was also verified that the abutment can easily retrieved from the implant, under the test conditions.

   All tested screws and abutments were successfully unscrewed and retrieved. The test was conducted in accordance with Adin internal protocol.

7) **UniFit regular platform dynamic loading test –** The tests were performed in order to determine the fatigue load (fatigue limit) for endosseous dental implants under "worst case" conditions and their prosthetic components in accordance with ISO 14801:2016 requirements. All of the success criteria were met.

8) **UniFit Torsion Testing -** The test was performed in order to determine the torsional yield strength and maximum torque of the worse-case implant/connecting part joints of UniFit implant system. All tested specimens met acceptance criteria for UniFit implant system torsional performance according per YY0315:2016.

9) **UniFit 6.00mm Implants - Pull-Out test –** The tests were performed to determining the axial pull-out strength of the Adin Short Implants as compared to the proposed predicate devices MIS short implants (K103089) according to the requirements of ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws in comparison with legally marketed device**.** The test met its acceptance criteria.

10) **Comparative Surface Area Analysis Before Surface Treatment between Adin's UniFit 6mmL Implants against MIS SEVEN Implants**– Adin's UniFit Short Implant's actual surface area before surface treatment was compared to both legally marketed devices (MIS short implants cleared under 510(k) K103089), at worst case implant variation. The total surface area measurements of the tested items were greater than the legally marketed reference item, the acceptance criteria was met.

11) **) Comparative Bone to Implant Contact Surface Area Analysis between Adin's UniFit 6mmL Implants against MIS Implants** – Contact surface area was analysed in comparison to legally marketed devices (MIS implants cleared under 510(k) K103089) at worst case implant variation. this test was conducted to determine the comparative equivalence of bone to implant contact (B.I.C.) for the tested item (Adin's UniFit short implant, 6.0 mm) and the reference item (MIS's SEVEN MF7-06420)

using state of the art 3D-CAD techniques utilizing two type of bone conditions: Hard Bone (Type I - referred as H.B) and Soft Bone (Type IV - referred as S.B). Test article, at both conditions of the bone, exceeded the MIS reference item in term of B.I.C volume and surface area.

12) **Single TMA – Fatigue Rationale –** the purpose of the Fatigue Rationale is to evaluate Fatigue limit of the Single TMA abutments assembled to designated Dental Implants including their compatible Screw (in accordance with ISO 14801:2016 – Dentistry – Implants – Dynamic fatigue test for endosseous dental implants) - The Single TMA and designated superstructures do not present any new worst-case when compare to the existing and approved TMA system.

13) **Fatigue testing of TiBase Abutments –** The worst-case combination of subject device implants, TiBase abutments and zirconia superstructure was tested according to ISO 14801 to determine that the subject devices are strong enough for their clinical application.

Biocompatibility

Biocompatibility tests were conducted in accordance with FDA Guidance for *Use of ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,* September 4, 2020, and; ISO 10993-1 for *biological evaluation* and; ISO 7405:2018 for *evaluation of medical devices used in dentistry. In-vitro* Cytotoxicity test of each surface treatment type, using the ISO Elution Method was conducted as well as Pyrogenic Material-Mediated and chemical extractions.

ISO 10993-5, ISO 10993-11 and ISO 10993-18 were used for the Cytotoxicity, Pyrogen Material-Mediated and chemical extractions, respectively.

Tests have been conducted at MDT Medical Device Testing GmbH using representative final implants including the OsseoFix™ surface treatment which went through Adin's entire production process, including packaging and sterilization (Gamma irradiation).

Tests of worst-case combinations of TiBase abutments, zirconia superstructure and the cement recommended in labeling showed that the devices were not cytotoxic in the test.

Gamma Irritation Sterilization

Adin's UniFit dental implants and cover screws are packed together and supplied sterile using gamma irradiation. They are intended for single use only.

The Gamma sterilization validation was conducted in accordance with ISO 11137-2:2013 for Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose in conjunction with ISO/TS 13004, in order to assure SAL (Sterility Assurance Level) of 10^{-6}

using VDmax 20kGy. The sterilization validation includes both the implants and the cover screws.

Cleaning and Steam Sterilization

Adin's superstructures (UniFit abutments and their screws) are single use and provided as non-sterile, therefore, the user is instructed to preform cleaning and steam-sterilization prior to clinical use in accordance with validated methods stated in the device's IFU.

Steam sterilization was validation in accordance with ISO 17665-1:2006 (Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices) and ISO 17665-2:2009 (Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1) was conducted using full cycle approach as detailed in Annex D4 of ISO 17665-1:2006 to assure a Sterility Assurance Level (SAL) of 10^{-6}.

Disinfection

Adin's ball caps are part of the Overdenture Ball Attachment System and are provided as non-sterile; Therefore, disinfection is to be conducted before clinical use by the clinician in accordance with validated methods stated in the IFU accompanying the device.

The disinfection process validation was conducted with accordance with ISO 17664-1:2021 (Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices) and AAMI TIR12:2020 (Designing, Testing, And Labeling Medical Devices Intended for Processing by Health Care Facilities: A Guide for Device Manufacturers.

Shelf-Life, Packaging and Transportation

Shelf-life tests were conducted to ensure 5 years shelf life under both accelerated and real-time aging. Shelf-life as performed in accordance with ISO 11607-1 for Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems. This validation confirmed that the sterility of Adin's sterile products will remain throughout the device shelf life and after packaging and transportation.

8. SUBSTANTIAL EQUIVALENCE

Adin's UniFit Dental Implant System is substantially equivalent to the predicate devices selected in terms of indication for use, technology, performances, design, place of use, patient population and nature of body contact.

The substantial equivalent decision was received based on the following comparisons with the predicate devices:

Table 5-1: Substantial Equivalence of Adin's *Dental Implants System* with Predicate Device (Dental Implants)

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
Classification	**Class:** II **Product code:** DZE (primary) NHA (secondary) **Regulation No.:** 872.3640	**Class:** II **Product code:** DZE (primary) NHA (secondary) **Regulation No.:** 872.3640	**Class:** II **Product code:** DZE (primary) NHA (secondary) **Regulation No.:** 872.3640	**Class:** II **Product code:** DZE (primary) NHA (secondary) **Regulation No.:** 872.3640	**Class:** II **Product code:** DZE **Regulation No.:** 872.3640	**Class:** II **Product code:** DZE (primary) NHA (secondary) **Regulation No.:** 872.3640	
Indications For Use	UniFit Dental Implants are intended for surgical placement in the maxillary and/or mandibular arch to	Touareg CloseFit™ Dental Implants are intended for surgical placement in	Adin Dental Implants are intended for surgical placement in the maxillary and/or	MIS dental implant system is intended to be surgically placed in the bone of the upper or	MIS dental implants are intended to be surgically placed in the bone of the	Straumann® BLX Implants are suitable for endosteal implantation in the upper and	The subject device has the same indication as the primary predicate

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
	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.	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	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.	lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.	upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function. When a one stage surgical procedure is applied, the	lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX implants can be placed with immediate function on single-tooth applications when good primary stability is	device and the reference devices, with only minor differences in wording which do not affect the indications for use and does not raise new safety issues. Limitation exists for MIS narrow implants in

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
	UniFit short implants are 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.#	loaded when good primary stability is achieved and with appropriate occlusal loading.		Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially dentulous jaws, to provide support for prosthetic devices such as artificial	implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. MIS short implants are to be used only with straight abutments.	achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	OD of 3.3mm (K172505) does not apply to the UniFit implant since the lowest OD is 3.5mm.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
				teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.			
Patient population	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Edentulous or partially edentulous patients	Identical to the primary predicate device and the reference devices.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
Sterilization	Gamma Irradiation (implants and cover screw only)	Gamma Irradiation (implants and cover screw only)	Gamma Irradiation (implants and cover screw only)	Gamma Irradiation (implants and cover screw)	Gamma Irradiation (implants and cover screw)	Gamma Irradiation (implants)	Identical to the primary predicate device and the reference devices.
Nature of body contact	Implant in bone/tissue contact for long term duration (>30 d)	Implant in bone/tissue contact for long term duration (>30 d)	Implant in bone/tissue contact for long term duration (>30 d)	Implant in bone/tissue contact for long term duration (>30 d)	Implant in bone/tissue contact for long term duration (>30 d)	Implant in bone/tissue contact for long term duration (>30 d)	Identical to the primary predicate device and the reference devices.
Prescription or Over-the-Counter (OTC)	Prescription	Prescription	Prescription	Prescription	Prescription	Prescription	Identical to the primary predicate device and the

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
							reference devices.
Single use	Yes	Yes	Yes	Yes	Yes	Yes	Identical to the primary predicate device and the reference devices.
Operation Principle	Single or Two-Stages procedure (immediate or delayed loading)	Single or Two-Stages procedure (immediate or delayed loading)	Single or Two-Stages procedure (immediate or delayed loading)	Single or Two-Stages procedure (immediate or delayed loading)	Single or Two-Stages procedure (immediate or delayed loading)	Single or Two-Stages procedure (immediate, early, or late implantation) (Appendix F, page 2, from published	Identical to the primary predicate device and the reference devices.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
						Instructions for Use, Section 3. Pg. 2)	
Placement Method	Placing the implant in the jaw bone immediately after drilling	Placing the implant in the jaw bone immediately after drilling	Placing the implant in the jaw bone immediately after drilling	Placing the implant in the jaw bone immediately after drilling	Placing the implant in the jaw bone immediately after drilling	Placing the implant in the jaw bone immediately after drilling	Identical to the primary predicate device and the reference devices.
Self-Tapping	Yes	Yes	Yes	Yes	Yes	Information not available	Identical to the primary predicate device and the reference devices

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
							(excluding K173961).
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium-13 Zirconium alloy (Roxolid®)	Identical to the primary predicate device and the reference devices (excluding K173961).
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Biocompatible	Identical to the primary predicate device and the reference devices.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
Shape	Screw type	Screw type	Screw type	Screw type	Screw type	Screw type (Appendix F, page 113, which is the published Technical Information for Straumann, section 2, page 6)	Identical to the primary predicate device and the reference devices.
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Internal hexagon	Conical with indexes	Internal hexagon	Conical Torx internal connection	Identical to the reference devices K172505 and K173961.
Surface Treatment	OsseoFix™ Calcium Phosphate	OsseoFix™ Calcium Phosphate	AB/AE	Anodized, sand blasted and acid etched	Sand blasting & acid etching	Hydrophilic SLActive®	Identical to the primary predicate

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
							device K112585.
Length	3.5mmD: 8, 10, 11.5, 13, 16, 18mm. 3.75mmD: 8, 10, 11.5, 13, 16, 18 mm. 4.3, 5mmD: 6, 8, 10, 11.5, 13, 16, 18 mm. 6mmD: 6, 8, 10, 11.5, 13mm.	3.5, 4.3, 5mmD: 8, 10, 11.5, 13, 15, 18 mm	3.5, 3.75, 4.2, 5, 6mmD: 8, 10, 11.5, 13, 16, 18mm	3.3mmD: 10, 11.5, 13 and 16 mm	4.2, 5, 6mmD: 6.0 mm	4.5mmD: 6, 8, 10, 12, 14, 16, 18 mm 5.5, 6.5mmD: 6, 8, 10, 12 mm	In the range of diameters of the primary predicate device and the reference devices.
Outer Diameter (OD)	3.5, 3.75, 4.3, 5, 6mm	RP 3.5mm WP 4.3, 5mm	Touareg-S Model: 3.5, 3.75, 4.2, 5, 6mm	3.3mm	4.2, 5, 6mm	4.5, 5.5, 6.5mm	In the range of diameters of the primary predicate device and the

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
							reference devices.
Packaging (Microbial Barrier)	Sterile barrier Protective Tube	Sterile barrier Protective Tube	Sterile barrier Protective Tube	Information not available	Information not available	Information not available	Identical to the primary predicate device and the reference devices (for which information is available).

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System,**	**Adin Dental Implants System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**MIS MIS Short Implants**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	**K103089**	**K173961**	
Shelf-Life	5 years	5 years	5 years	5 years	Information not available	5 years	Identical to the primary predicate device and the reference devices (for which information is available).

Table 5-2: Substantial Equivalence of Adin's *Dental Implants System* with Predicate Device (Healing Abutments)

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System**	**Adin Dental Implants System**	**Straumann BLX Implant System**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K173961**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Grade 4	Identical to the primary predicate device and the reference devices (excluding K173961)
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Internal hexagon	Conical Torx internal connection	Identical to the reference device K173961.
Diameter	3.5-5.5mm#	3.5-5.5mm	4.5mm	4.0-7.5mm	Identical to the primary device and within the range of all the comparable cleared devices (primary predicate and reference devices).
Height above implant connection	2.0-6.0mm#	2.0-6.0mm	2.0-6.0mm	2.75-7.5mm	Identical to the primary and Adin's reference device and within the range of all the comparable cleared devices (primary predicate and reference devices).
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	Non-sterile provided. Sterilized by end user.	Sterile using gamma irradiation	Identical to the primary predicate device and the reference devices (excluding K173961, which does not affect substantial equivalence, since both features are feasible and cleared).

Table 5-3: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Devices (Cement Retained Abutments)

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System**	**Adin Dental Implants System**	**MIS MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Grade 4	Identical to the primary predicate device and the reference devices (excluding K173961).
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Internal hexagon	Conical with indexes (Torx)	Identical to the reference device K172505.
Diameter	4.0-5.5mm#	4.0-5.5mm	3.9-5.0mm	3.3-5.0mm	Identical to the primary device and within the range of all the comparable cleared devices (primary predicate and reference devices).
Gingival Height	1.0-3.0mm	1.0-3.0mm	0.6-4.0mm	Information not available	In the range of the primary predicate device and the reference devices (excluding K172505).

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System**	**Adin Dental Implants System**	**MIS MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K081751**	**K172505**	
Angulation	Up to 25°	Up to 15°	Up to 25°	Up to 25°	In the range of the primary predicate device and within the range of all the comparable cleared devices (primary predicate and reference devices).
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	Non-sterile provided. Sterilized by end user.	Non-sterile provided. Sterilized by end user.	Identical to the primary predicate device and the reference devices

Table 5-4: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Devices (Screw Retained Abutments – TMA, STMA and Flat Connection Abutments)

	Subject Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg NP CloseFit™ Dental Implant System**	**MIS MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
510k Number	**K223714**	**K140293**	**K172505**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Identical to the reference devices
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Conical with indexes (Torx)	Identical to the reference device K172505
Diameter	4.9mm#	4.9mm	4.8mm	Identical to K140293
Gingival Height	1.0-5.0mm	1.0-5.0mm	1.0-5.0mm	In the range of the reference devices
Angulation	Up to 30°	Up to 30°	Up to 30°	Identical to the reference devices
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	Sterile using gamma irradiation	Identical to K140293 (excluding K172505, which does not affect substantial equivalence, since both features are feasible and cleared).

Table 5-5: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Devices (UCLA Abutments, Screw or Cement Retained)

	Subject Device	Primary Predicate Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin Touareg CloseFit™ Dental Implant System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
	K223714	**K112585**	**K172505**	
Material	Titanium Alloy (Ti-6Al-4V-ELI) + POM-C (burnout plastic sleeve, Polyoxymethylene) + Ti-6Al-4V-ELI screw	Titanium Alloy (Ti-6Al-4V-ELI) + POM-C (burnout plastic sleeve, Polyoxymethylene) + Ti-6Al-4V-ELI screw	Gold Alloy + POM (burnout plastic sleeve, Polyoxymethylene) + Ti-6Al-4V-ELI screw	Identical to the primary predicate device K112585
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Conical with indexes (Torx)	Identical to the reference device K172505
Diameter	4.7-5.2mm#	4.7-5.2mm	3.3-5.0mm	Identical to the primary device and within the range the comparable cleared devices (primary predicate and reference devices).
Gingival Height	1.5mm	1.36-1.5mm	Information not available	In the range of the primary predicate device
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	Non-sterile provided. Sterilized by end user.	Identical to the primary predicate device and the reference device

Table 5-6: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Devices (Ball Attachments)

	Subject Device	Primary Predicate Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Adin's Touareg CloseFit™ Dental Implant System**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
510(k) Number	**K223714**	**K112585**	**K172505**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI + Titanium Nitride (TiN) coating	Identical to the primary predicate device
Connection	Conical "star" (Torx) internal connection	Conical hexagon	Conical with indexes (Torx)	Identical to the reference device K172505
Diameter	3.1mm#	3.1-3.5mm	3.3-5.0mm	In the range of the primary predicate device and the reference device
Gingival Height	0.5-5.0mm	0.5-5.0mm	1-5mm	In the range of the primary predicate device and the reference device
Angulation	Straight	Straight	Up to 15°	In the range of the primary predicate device and the reference device
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	Non-sterile provided. Sterilized by end user.	Identical to the primary predicate device and the reference device

Table 5-7: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Devices (TMA and STMA Cementing Cone)

	Subject Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**MIS CONNECT Superstructures (Cementing Caps)**	**Neobiotech Co., Ltd., IS Multi-Unit Abutment System (Multi-Unit Abutment Cylinder)**	**TruAbutment Inc., URIS OMNI Narrow System & Prosthetic (Multi-unit Base)**	**Equivalence Discussion**
510(k) Number	**K223714**	**K173326**	**K210903**	**K200817**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy – 6Al-4V-ELI	Identical to the reference devices
Connection	Connect to Adin's Screw Retained Abutments (TMA, STMA) mounted on an Adin Unifit Conical Connection Implant	Connects to MIS CONNECT abutment mounted on a MIS Conical Connection Dental Implant	Connected with Multi Unit Abutment with Cylinder Screw	Not mentioned in the summary	Identical to the reference device K173326
Diameter	4.9mm#	4.8mm	4.8mm	5.0mm	In range of the reference devices
Length	4.9mm	3.3mm	5.0mm	5.0mm	In range of the reference devices
Angulation	Straight	Straight	Straight	Straight	Identical to the reference devices
Sterilization	Non-sterile provided. Sterilized by end user.#	Non-sterile provided. Sterilized by end user.	End-User Moist Heat Sterilization	End-User Moist Heat Sterilization	Identical to the reference devices

Table 5-8: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Device (Ti Bases)

	Subject Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**DESS Dental Smart Solutions Terrats Medical SL, DESS Aurum Base** **(Information also obtained from company IFU FDA version)**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments, cleared under**	**Equivalence Discussion**
510(k) Number	**K223714**	**K212628**	**K172505**	
Material	Ti-6Al-4V-ELI, Argen Z Ultra Zirconia, Panavia V5 Cement	Ti-6Al-4V ELI, Y-TZP per ISO 13356, Ivoclar Vivadent Multi-Link cement	Titanium Grade 4	Same as Reference Device cleared under K212628
Connection	Conical "star" (Torx) internal connection	Internal Hex Conical	Conical with indexes (Torx)	Same as Reference Device cleared under K172505
Diameter	4.5-6.5mm	4.5 – 6.5mm	3.3-5.0mm	In range of the reference devices
Sterilization	Non-sterile/End user sterilized	Non-sterile/End user sterilized	Non-sterile/End user sterilized	Identical to the reference device
Design limits	Minimum wall thickness – 0.5 mm Minimum post height for single-unit restorations – 4.0 mm gingival height – 1-4 mm	Minimum wall thickness – 0.4 mm Minimum post height for single-unit restorations – 4.0 mm gingival height – 0.5–6.0 mm	Not Applicable, since not customizable but serves to support the specification limits.	In range of the Reference Device cleared under K212628

Table 5-9: Substantial Equivalence of Adin's *UniFit Dental Implants System* with Predicate Device (Ti Blank)

	Subject Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Imagine Milling Technologies, LLC's MIST IC abutments (PREFIT)**	**DESS Dental Smart Solutions Terrats Medical SL, Pre-milled Blank Ti (Information also obtained from company IFU FDA version)**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
	K223714	**K18224**	**K212628**	**K172505**	
Material	Titanium Alloy – 6Al-4V-ELI	Titanium Alloy, Zirconia	Titanium alloy (Ti-6Al-4V)	Titanium Grade 4	Same as Reference Device cleared under K212628
Connection	Conical "star" (Torx) internal connection	Not mentioned in the summary	Conical internal hex connection	Conical with indexes (Torx)	Same as Reference Device cleared under K172505
Implant/Abutment connection Diameter	2.9mm	3.5-5.0mm	2.3-6.0	3.3-5.0mm	In range of the reference devices
Design limits				Not Applicable, since not customizable but serves to support the specification limits.	In range of the reference devices
Minimum Abutment wall thickness	0.5mm	0.5mm	0.45 mm		
Maximum Milled abutment height	10	Not mentioned in the summary	19		
Maximum Emergence profile diameter	13	Not mentioned in the summary	14		

	Subject Device	Reference Device	Reference Device	Reference Device	
Feature	**Adin UniFit Dental Implant System**	**Imagine Milling Technologies, LLC's MIST IC abutments (PREFIT)**	**DESS Dental Smart Solutions Terrats Medical SL, Pre-milled Blank Ti (Information also obtained from company IFU FDA version)**	**MIS's MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection Abutments**	**Equivalence Discussion**
	K223714	**K18224**	**K212628**	**K172505**	
Maximum Abutment angulation	20°	30°	Straight		
Minimum post height for single-unit restoration	4.0	4.0	4.0		
Maximum Emergence profile height/Maximum gingival height	6.0	5.0	6.0		
Minimum gingival height	0.5 mm	0.5 mm	0.5 mm		
Sterilization	Non-sterile/End user sterilized	Non-sterile/End user sterilized	Non-sterile/End user sterilized	Non-sterile/End user sterilized	

Substantial Equivalence Discussion:

The proposed Adin UniFit Dental Implant System has the same indications for use, technological characteristics, mode of operation and performance specifications as the above identified Predicate and Reference devices. The proposed device has the same intended use as the Predicate and Reference devices and is placed using the same methodology as all selected predicate devices. The proposed and Predicate and Reference devices all function in the same manner providing support for prosthetic devices in the upper or lower jaw. Similarities and differences were addressed by Adin. It can be seen that certain differences presented in the comparison table are all within the range of one or more Predicate or Reference device(s). Therefore, it was concluded that Adin UniFit Dental Implant System and the predicate devices are substantially equivalent.

9. CONCLUSIONS

Adin UniFit Dental Implant System, which is the subject of this 510(k) Submission, is substantially equivalent to the predicate device indicated above. The device has met its requirements and labeling claims per its intended use. The device does not introduce new risks and does not present any new adverse health effects or safety potential risks to patients when used as intended.

Therefore, it was concluded that the overall evaluation of the device performance demonstrates that it is as safe and as effective as the predicate devices and therefore substantially equivalent.