July 18, 2019

Ziacom Medical SL
℅ Alvaro Idiago
Quality and S&R Manager
Calle Búhos, 2
Pinto, 28320
SPAIN

Re: K182908
Trade/Device Name: Ziacom Dental Implant Systems
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 13, 2019
Received: June 17, 2019

Dear Alvaro Idiago:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182908

Device Name
Ziacom Dental Implant Systems

Indications for Use *(Describe)*
Ziacom Dental Implant Systems are intended to be surgically placed in the bone of the mandibular or maxillary jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function and to aid in prosthetic rehabilitation. Ziacom Dental Implant Abutments are intended to be used with Ziacom Dental Implants to aid in prosthetic rehabilitation.
The intended use for Ziacom Dental Implant Zinic® NP 3.30mm diameter is limited to replacement of mandibular incisors.

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) K182908 Summary
ZIACOM MEDICAL SL
Ziacom Dental Implant Systems

July 18, 2019

ADMINISTRATIVE INFORMATION

Manufacturer Name	ZIACOM MEDICAL SL Calle Búhos, 2 28320 Pinto Spain Telephone: +34 91723 33 06 Fax: +34 91723 33 07
Official Contact	Álvaro Idiago, Quality and S&R Manager

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Ziacom Dental Implant Systems
Common Name	Dental implant Dental implant abutment
Classification Name	Implant, endosseous, root form Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate:

K120414	OsseoSpeed™ Plus	Astra Tech AB

Reference Devices:

K092341	Low Profile Abutment	Biomet 3*i*, Incorporated
K133991	iSy® Implant	Altatec GmbH
K160244	System	Thommen Medical AG
K171795	VARIOunite	Thommen Medical AG
K150669	Thommen Implant System	Neoss Ltd.
K142211	OT EQUATOR®	Rhein '83 Srl
K072878	LOCATOR Implant Anchor	Zest Anchors, Inc.

INDICATIONS FOR USE

Ziacom Dental Implant Systems are intended to be surgically placed in the bone of the mandibular or maxillary jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function and to aid in prosthetic rehabilitation. Ziacom Dental Implant Abutments are intended to be used with Ziacom Dental Implants to aid in prosthetic rehabilitation.

The intended use for Ziacom Dental Implant Zinic® NP 3.30mm diameter is limited to replacement of mandibular incisors.

DEVICE DESCRIPTION

Zinic® and Zinic®MT implants are threaded, self-tapping, root-form dental implants manufactured from CP titanium Grade 4 conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)*. The implants have apical flutes, an internal hexagonal abutment interface and a conical bevel at the abutment interface. They are threaded internally for attachment of mating abutments, cover screws, healing abutments or temporary abutments. The coronal portion of the implant has a microthread design. The Zinic design is a straight implant, while Zinic MT implants are tapered in the apical 40% of the implant length. All implants have a grit blasted and acid etched surface, designated Osseonova Surface.

Implants and abutments with the same platform connection are compatible. Zinic and ZinicMT implants are available with following sizes:

Part Number	DESCRIPTION	Implant Length	Body Diameter	Platform Diameter	Internal Connection Diameter	Screw Size
ZSS3310	Zinic Implant NP Ø3,30X10mm	10	3.3	NP 3.2 mm	2.1	M1.6
ZSS3311	Zinic Implant NP Ø3,30X11,50mm	11.5				
ZSS3313	Zinic Implant NP Ø3,30X13mm	13				
ZSS3314	Zinic Implant NP Ø3,30X14,50mm	14.5				
ZSS3785	Zinic Implant RP Ø3,70X8,50mm	8.5	3.7	RP 3.5 mm	2.42	M1.8
ZSS3710	Zinic Implant RP Ø3,70X10mm	10				
ZSS3711	Zinic Implant RP Ø3,70X11,50mm	11.5				
ZSS3713	Zinic Implant RP Ø3,70X13mm	13				
ZSS3714	Zinic Implant RP Ø3,70X14,50mm	14.5				
ZSS4085	Zinic Implant RP Ø4,00X8,50mm	8.5	4			
ZSS4010	Zinic Implant RP Ø4,00X10mm	10				
ZSS4011	Zinic Implant RP Ø4,00X11,50mm	11.5				
ZSS4013	Zinic Implant RP Ø4,00X13mm	13				
ZSS4014	Zinic Implant RP Ø4,00X14,50mm	14.5				
ZSS4385	Zinic Implant RP Ø4,30X8,50mm	8.5	4.3			
ZSS4310	Zinic Implant RP Ø4,30X10mm	10				
ZSS4311	Zinic Implant RP Ø4,30X11,50mm	11.5				
ZSS4313	Zinic Implant RP Ø4,30X13mm	13				
ZSS4314	Zinic Implant RP Ø4,30X14,50mm	14.5				
ZSS4685	Zinic Implant WP Ø4,60X8,50mm	8.5	4.6	WP 4.5 mm	2.42	
ZSS4610	Zinic Implant WP Ø4,60X10mm	10				
ZSS4611	Zinic Implant WP Ø4,60X11,50mm	11.5				
ZSS4613	Zinic Implant WP Ø4,60X13mm	13				
ZSS5085	Zinic Implant WP Ø5,00X8,50mm	8.5	5			
ZSS5010	Zinic Implant WP Ø5,00X10mm	10				
ZSS5011	Zinic Implant WP Ø5,00X11,50mm	11.5				
ZSS5013	Zinic Implant WP Ø5,00X13mm	13				

Part Number	DESCRIPTION	Implant Length	Body Diameter	Platform Diameter	Internal Connection Diameter	Screw Size
ZSS3685M	ZinicMT® Implant RP Ø3,60X8,50mm	8.5	3.6	RP 3.5mm	2.42	M1.8
ZSS3610M	ZinicMT® Implant RP Ø3,60X10mm	10				
ZSS3611M	ZinicMT® Implant RP Ø3,60X11,50mm	11.5				
ZSS3613M	ZinicMT® Implant RP Ø3,60X13mm	13				
ZSS4085M	ZinicMT® Implant RP Ø4,00X8,50mm	8.5	4			
ZSS4010M	ZinicMT® Implant RP Ø4,00X10mm	10				
ZSS4011M	ZinicMT® Implant RP Ø4,00X11,50mm	11.5				
ZSS4013M	ZinicMT® Implant RP Ø4,00X13mm	13				
ZSS4485M	ZinicMT® Implant RP Ø4,40X8,50mm	8.5	4.4			
ZSS4410M	ZinicMT® Implant RP Ø4,40X10mm	10				
ZSS4411M	ZinicMT® Implant RP Ø4,40X11,50mm	11.5				
ZSS4413M	ZinicMT® Implant RP Ø4,40X13mm	13				
ZSS4885M	ZinicMT® Implant WP Ø4,80X8,50mm	8.5	4.8	WP 4.5mm		
ZSS4810M	ZinicMT® Implant WP Ø4,80X10mm	10				
ZSS4811M	ZinicMT® Implant WP Ø4,80X11,50mm	11.5				
ZSS4813M	ZinicMT® ImplantWP Ø4,80X13mm	13				

Zinic and ZinicMT implants are provided sterile to the end-user in a single-unit package, and are for single-patient, single-use only. They are provided in ZPlus packaging or Z2Plus packaging, attached to the ZPlus or Z2Plus Mount, respectively, or in NoMount packaging, without an implant mount. Packaging facilitates the aseptic handling and placement of the implant, with the mounts also capable of serving either as a provisional abutment or a definitive abutment. Z2Plus also can serve as a transfer for a Snap-On impression technique.

Subject device abutments include cover screws, healing abutments, provisional abutments, sculptable (prepable) abutments, conical abutments in straight and angled (15°, 25° and 30°) designs, castable abutments (CoCr base plus burn-out sleeve) in straight and angled (15°, 20°) designs, Basic and Unitary Basic abutments to serve as intermediate abutments between the implant and the prosthesis, XDrive multi-unit abutments in straight and angled (17°, 30°) designs.
All subject device abutments have the universal internal implant connection and are compatible with both implant lines, except that NP abutments are compatible only with Zinic NP implants (there are no ZinicMT NP implants). Abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401),* polyetheretherketone (PEEK) conforming to ASTM F2026 *Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications* or cobalt-chromium-molybdenum alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539).*

Subject device abutments include two overdenture abutments (Kirator,ZM-Equator). Kirator overdenture abutments are straight prosthetic abutments that are used for the retention of preexisting or newly fabricated full dentures (classified as implant-retained mucosupported overdentures). ZM-Equator abutments are straight prosthetic abutments used for the retention of tissue-supported implant-retained prostheses. Its is indicated in rehabilitation of narrow ridges and/or reduced vertical dimension Each overdenture abutment is the "male" part of a removable prosthesis retention which contains a metal

housing cap that incorporate plastic retention with different degrees of elastic retention. Abutments and housing caps are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* The different plastic retentions are manufacture from Kepital, Rilsan bmno and Pebax.

All abutments are provided non-sterile to the end-user in a single-unit package, and are for single-patient, single-use only.

Clinical screws used to attach abutments and prosthetic components to implants are available with an M1.6 thread and 8 mm length to fit NP abutments and implants and with an M1.8 thread and 7.85 mm length to fit RP and WP abutments and implants. They are available in a machined Ti-6Al-4V design and in a design that is hard anodized to provide anti-loosening characteristics, designated Kiran®. Machined titanium alloy screws are anodized for identification, with the M1.6 thread screw that fits NP abutments and implants colored yellow and the M1.8 thread screws that fit RP and WP abutments and implants colored blue. Kiran screws are dark grey.

A TX30 Torx screw is available for retention of the TX30 Mechanized Angled Abutment. It incorporates a 6-lobed internal feature mating with a 6 lobed spherical tip screwdriver to permit driving the screw with the driver inserted through the angled portion of the restoration. It is provided with the Kiran hard anodizing treatment.

Additional screws are available to attach prosthetic components to Basic abutments and to XDrive abutments. Basic screws have an M1.8 thread and are 4.3 mm long, while XDrive screws have an M1.4 thread and are 3.5 mm long. Each is available as an anodized machined titanium alloy screw or as a Kiran screw with the hard anodizing treatment.

PERFORMANCE DATA

Mechanical testing was performed to ensure that the strength of the Ziacom Implant System is appropriate for its intended use. After determination of the worst-case construct, static and dynamic testing were performed according to ISO 14801 *Dentistry - Implants - Dynamic loading test for endosseous dental implants.*

To characterize the grit blasted and double acid etched surface that is applied to the endosseous portion of Zinic and ZinicMT implants, implants were treated by the same process as is used for the subject devices, subjected to the same packaging and sterilization process that are used for the subject devices and were analyzed and compared with the same analysis on samples that had not undergone packaging and sterilization. Surface characterization included scanning electron microscopy (SEM) in both conventional and backscattered electron mode to evaluate surface topography and X-ray Photoelectron Spectroscopy (XPS) to evaluate surface chemistry. In addition, cytotoxicity testing was performed. The study concluded that:

- the surface treatment process performed on subject device implants promotes a modification of the pristine machined surface topography
- the obtained roughness is in agreement with accepted and used values for dental implant surfaces
- the adopted process and the following cleaning steps yield a clean surface, in chemical terms
- the complete production cycle, including shipment to Ziacom, relevant packaging and sterilization, does not spoil or modify the surface properties obtained by the treatment
- dental implants treated according to this process are non-cytotoxic
- acceptance criteria for surface chemistry and surface roughness have been defined.

DISCUSSION OF NON CLINICAL TESTS

Cytotoxicity Evaluation

Cytotoxicity testing was performed on the finished Ziacom Dental Implant System components according to ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, and ISO 10993-12 *Biological evaluation of medical devices – Part 12:Sample preparation and reference materials*. Based on the results of these tests the subject device components are considered safe and suitable for their intended use.

Sterilization Validation

The sterile Subject Device (implants) are sterilized by beta irradiation at a nominal dose of 25 kGy (2.5 Mrad). Sterilization has been validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to 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 and ISO 11137-2 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose.*

Abutments and other components are provided non-sterile, to be sterilized by the end-user. The recommended sterilization cycle is moist heat, gravity autoclave at 132°C/270°F for a minimum of 15 minutes using a wrap or pouch, with 15-30 minutes dry time. This cycle has been validated by the overkill method to a sterility assurance level (SAL) of 10^{-6} according to 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* and ISO TS 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1.*

Sterile Barrier Validation

Accelerated aging to validate sterile barrier of subject device was conducted after packaging, sterilization and transportation simulation in accordance with ISO 11607-1 (2006), *Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems [Including: Amendment 1 (2014)]*, ISO 11607-2 (2006), *Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes [Including: Amendment 1 (2014)]* and ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices. After accelerated aging, the package samples were evaluated by dye penetration according to ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*

Bacterial Endotoxin Testing

For the subject device components provided sterile to the end-user bacterial endotoxin testing was performed to ensure that the subject device meets the pyrogen limit specifications. The Limulus amebocyte lysate (LAL) test for detection and quantitation of bacterial endotoxin was conducted in accordance with the United States Pharmacopeia <85>. The level of bacterial endotoxins was determined to be less than 20 EU/Device

EQUIVALENCE TO MARKETED DEVICE

ZIACOM MEDICAL SL submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Primary Predicate:

K120414	OsseoSpeed™ Plus	Astra Tech AB

Reference Devices:

K092341	Low Profile Abutment	Biomet 3i, Incorporated
K133991	iSy® Implant System	Altatec GmbH
K160244	VARIOunite	Thommen Medical AG
K171795	Thommen Implant System	Thommen Medical AG
K150669	Neoss TiBase and CoCr Abutments	Neoss Ltd.
K142211	OT EQUATOR®	Rhein '83 Srl
K072878	LOCATOR Implant Anchor	Zest Anchors, Inc.

The primary predicate device K120414 is included for substantial equivalence of the subject device implant and abutment designs. The subject device implants have similar design to that of implants in K120414, including the external thread, cutting flutes, microthread collar, use of an internal antirotational feature and internal thread to mate with abutment screws. Subject device implant body diameters and lengths are within the range of those cleared in K120414 and the material from which the implants are manufactured, unalloyed titanium, is the same. In addition, the primary predicate includes abutments designs and screws similar to those of the subject device and made from the same Ti-6Al-4V alloy

Reference device K092341 includes a short abutment post for single-unit and multi-unit restorations and includes angled low-profile abutments. Reference device K133991 includes an implant mount that also can be used for a restoration, as well as including a grit blasted and acid etched (GBE) implant surface. Reference devices K160244 and K171795 include a straight titanium abutment (VARIOunite) that can be used for fabrication of a temporary restoration (VARIOtemp) or a permanent restoration (VARIOflex).

Reference device K150669 includes CoCr alloy abutments made from the same material as subject device CoCr abutments.

Reference device K142211 has similar design to that of subject device. Subject device abutment body diameters and lengths are within the range of those cleared in K142211 and the material from which the abutments are manufactured is the same. Reference device K142211 includes the same designed accessories that the subject device and the retention caps are made in the same material and dimensions.

Reference device K072878 has similar design to that of subject device. Subject device abutment body diameters and lengths are within the range of those cleared in K072878 and the material from which the abutments are manufactured is the same. Reference device K072878 includes the accessories with similar design those the subject device (Metal housing and retention caps).

The subject device and the predicate devices all incorporate the same materials and encompass similar ranges of dimensions. Predicate and reference device support substantial equivalence so the implants, abutments, materials, accessories and technologies in manufacture are similar and, in most of case, identical. All subject device components are for single-patient, single-use, and implants are provided sterile. Subject device abutments are provided non-sterile and are to be moist heat sterilized by the end user. Similarly, the primary predicate device K120414 includes abutments that are provide non- sterile and are to be most heat sterilized by the end user.

The Indications for Use Statement for the subject device is similar to that of the primary predicate K120414 for implants and for abutments. Differences in wording do not change the intended use of the devices, which is to provide support for prosthetic restorations.

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are similar to those of the primary predicate and reference devices and that the effects

on biocompatibility of any differences that might exist in processing and storage conditions have been evaluated according to ISO 10993-1, including testing according to ISO 10993-5.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing according to ISO 14801 Dentistry – Implants – Dynamic fatigue test for endosseous dental implants was performed. Dynamic testing was performed on worst-case subject device constructs. The results from the testing demonstrated fatigue performance of the subject device to be substantially equivalent to that of the predicate devices and to generally accepted performance requirements.

The basis for the belief of ZIACOM MEDICAL SL that the subject device is substantially equivalent to the predicate devices is summarized in the following Table of Substantial Equivalence.

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials and coatings, and
- has similar packaging and is sterilized using the same materials and processes.

Below are summary tables comparing the Indications for Use and the technological characteristics of the subject device and the predicate devices.

CONCLUSION

The subject device and the predicate and reference devices have the same intended use, have similar technological characteristics, and are made of similar materials and coatings. The subject device and the predicate and reference devices encompass the same range of physical dimensions, including diameter and length of the implants, diameter and angulation of the abutments, and the materials and designs of accessories of abutments. The subject device and the predicate and reference devices are packaged in similar materials and sterilized using similar methods.

The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.

Table 12.1 Table of Substantial Equivalence – Indications for Use Statement

	Indications for Use Statement
Subject Device	
K182908 Ziacom Dental Implant System Ziacom Medical S.L.	Ziacom Dental Implant Systems are intended to be surgically placed in the bone of the mandibular or maxillary jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function and to aid in prosthetic rehabilitation. Ziacom Dental Implant Abutments are intended to be used with Ziacom Dental Implants to aid in prosthetic rehabilitation. The intended use for Ziacom Dental Implant Zinic® NP 3.30mm diameter is limited to replacement of mandibular incisors.
Primary Predicate Devices	
K120414 OsseoSpeed™ Plus Astra Tech AB	Implants: The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols: • replacing single and multiple missing teeth in the mandible and maxilla, • immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge, • especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective, • immediate loading in all indications, except in single tooth situations on implants shorter than 8 mm, or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate. The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors. Abutments: Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Plus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, bridges or overdentures. Atlantis Abutments: The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous; patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous; implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous; patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.

Reference Devices	Indications for Use Statement
K092341 Low Profile Abutment Biomet 3*i*, Incorporated	BIOMET *3i* Low Profile Abutments are intended for use as accessories to endosseous dental implants to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.
K133991 iSy® Implant System Altatec GmbH	iSy® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
K160244 VARIOunite Thommen Medical AG	VARIOflex Thommen Medical VARIOflex Abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures. VARIOtemp Thommen Medical VARIOtemp Abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures.
K171795 Thommen Implant System Thommen Medical AG	Implant: The ELEMENT PF 3.0 is suitable for use in one-stage or two-stage surgical techniques for restoring chewing function. The ELEMENT PF 3.0 is suitable for immediate implantation and restoration in case of replacement of several teeth; prerequisites are good primary stability and appropriate occlusal loading. The ELEMENT PF 3.0 must only be used for replacement of the lateral incisors of the upper jaw and the central and lateral incisors of the lower jaw. VARIOunite PF 3.0: Thommen Medical VARIOunite abutments PF 3.0 are only used in conjunction with the ELEMENT PF 3.0 and are for fabrication of provisional and final crowns in the anterior maxilla and mandible (upper lateral incisors, lower anterior teeth). Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture. VARIOunite: Thommen Medical VARIOunite abutments are intended to be used in conjunction with Thommen System dental implants in the maxillary and/or mandibular arch to provide support for crowns, bridges and overdentures. Digitally designed abutments for use with Thommen VARIOunite are intended to be sent to a Thommen validated milling center for manufacture.
K150669 Neoss TiBase and CoCr Abutments Neoss Ltd.	Neoss TiBase: Neoss Abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation The Neoss TiuBase is compatible with the Sirona Dental Systme inCoris ZI Meso L. All digitally designed copings and/or crowns for use with the Neoss TiBase Abutments are to be designed and milled using the Sirona Dental CAD/CAM System. Neoss CoCr Abutments: Neoss abutments are designed to be connected to the Neoss Implants and intended for use as an aid in prosthetic rehabilitation.

Reference Devices	Indications for Use Statement
K142211 OT EQUATOR® Rhein ’83 Srl	The OT Equator® is designed as an endosseous dental implant retentive component used to retain a complete or partial denture. The OT Equator® is screwed into an endosseous implant in the mandible or maxilla.
K072878 LOCATOR Implant Anchor Zest Anchors, Inc.	The LOCATOR Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla. denture. The OT Equator® is screwed into an endosseous implant in the mandible or maxilla.

Table 12.2 Tables of Substantial Equivalences – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	K182908 Ziacom Dental Implant System Ziacom Medical S.L.	K120414 OsseoSpeed™ Plus Astra Tech AB	K092341 Low Profile Abutment Biomet 3*i*, Incorporated	K133991 iSy® Implant System Altatec	K160244 K171795 VARIOunite, Thommen Implant System Thommen Medical AG	K150669 Neoss TiBase and CoCr Abutments Neoss Ltd.
Reason for Predicate	NA	Implant, abutment designs, material	Short abutment post for single-unit restoration	Mount used for temporary restoration, GBE surface	Used for temporary or permanent restoration (VARIOunite)	CoCr Alloy
Design						
Implant Diameter (mm)	3.3, 3.7, 4, 4.3, 4.6, 5.0	3.0, 3.6, 4.2, 4.8, 5.4	NA	3.8, 4.4, 5.0	NA	NA
Implant Length (mm)	8,5 10, 11.5, 13, 14.5	6, 8, 9, 11, 13, 15, 17	NA	9, 11, 13	NA	NA
Implant/Abutment Platform Diameter (mm)	NP (3.2), RP (3.5), WP (4.5)	3.0, 3.6, 4.2, 4.8, 5.4	3.4, 4.1, 5.0	3.8, 4.4, 5.0	3.0, 3.5, 4.0, 4.5, 5.0, 6.0	4.1
Abutment Angle	0°, 15°, 17°, 20°, 25°, 30°	Up to 30°	0°, 17°, 30°	Up to 20°	Up to 20°	Up to 20°
Interface Connection	Internal	Internal	Internal/External	Internal	Internal	Internal
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
Material						
Implant	Unalloyed Titanium	Unalloyed Titanium	NA	Unalloyed Titanium	NA	NA
Implant Surface	Grit blasted, acid etched (GBE)	OsseoSpeed	NA	GBE	NA	NA
Abutment	Titanium alloy, PEEK, CoCr alloy	Titanium alloy, PEEK	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy, CoCr alloy
Screw	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy	Titanium alloy