August 23, 2024

Proimtech Saglik Urunleri Anonim Sirketi
Hakan Cevik
General Manager
Imes Sitesi, No:3 Dudullu Osb Mahallesi Imes 305.Sokak
Istanbul, Istanbul 34773
TURKEY

Re: K231100
Trade/Device Name: Proimtech Dental Body Implant, Proimtech Abutment, Proimtech Healing Cap, Proimtech Abutment Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 25, 2023
Received: July 31, 2024

Dear Hakan Cevik:

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)*
K231100

Device Name
Proimtech Dental Body Implant, Proimtech Abutment, Proimtech Healing Cap, Proimtech Abutment Screw

Indications for Use *(Describe)*
Indications for use Bilimplant® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

Bilimplant Abutments and Prosthetic parts are intended for use with Bilimplant Dental Implants in the maxillary and / or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.

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
510k K231100
Dental Body Implant
Proimtech Saglik Urunleri Anonim Sirketi
August 23, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name: PROIMTECH SAGLIK URUNLERI ANONIM SIRKETI
Adress: Dudullu OSB Mahallesi İmes Sanayi Sitesi 305. Sokak C Blok NO:3, Ümraniye, İstanbul
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Official Contact: Hakan Cevik, General Manager of Proimtech Saglik Urunleri Anonim Sirketi
Phone Number: +90 535 355 51 00
E-Mail: hakancevik@bilimplant.com

DEVICE NAME AND CLASSIFICATION

Device Trade Name: Proimtech Dental Body Implant, Proimtech Abutment, Proimtech Healing Cap, Proimtech Abutment Screw

Common Name: Dental Body Implant, Abutment, Healing Cap, Abutment Screw,

Classification Name: Dental Body Implant, Endosseous dental implant (21 CFR 872.3640),

Device Class: II
Product Code: DZE
Regulation Number: 872.3640
Review Panel: Dental

Legally Marketed Device to Which Claim Substantial Equivalence:

for; Primary Predicate Device Implant Body: K140878, STRAUMANN BONE LEVEL TAPERED IMPLANT

for; Reference Device Implant Body: K173961, Straumann® BLX Implant System

for; Reference Device Implant Body: K212533, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants

for; Reference Device Implant Body: K130222, Straumann Dental Implant System SLActive and Roxolid Product Families

for; Reference Device Abutment: K160850, Nucleoss Abutment System SANLILAR TIBBI CIHAZLAR MED. KIM.SAN.TIC.LTD.STI

for; Reference Device Abutment Screw: K182448, MegaGen Implant Co., Ltd.

for; Reference Device Healing Cap: K052957, Dentium Implantium® & SuperLine® Prosthetics

for; Reference Healing Cap: K051636, CAMLOG Dental Implant Abutments, Healing Caps, and Accessories

INDICATIONS FOR USE STATEMENT

Dental Body Implant:

Indications for use Bilimplant® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth restorations and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.

For Abutment

Healing Cap

Abutment Screw:

Indications:

Bilimplant Abutments and Prosthetic parts are intended for use with Bilimplant Dental Implants in the maxillary and / or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.

2. Intended Use

The Bilimplant® dental implants and abutments, which are models within the Proimtech Implant and Abutment system, are intended for oral implantation to provide a support structure for connected prosthetic devices.

PRODUCT NAME	INTENDED USE
Bone Level Implant	Thanks to its design features, it is placed completely at the bone level. It is produced to be applied in different bone types and different regions (anterior and posterior) in the lower and upper jaw. Since it is at the bone level, it can be used for more aesthetic results, especially in the front areas of the jaws (in the areas on the smile line).
Tissue Level Implant	The Tissue Level Implant has a 2.3 mm machined collar. It can be used in posterior applications in the upper and lower jaw where there are no aesthetic concerns, in different bone types and especially in cases with high gingival amount in order to facilitate prosthetic stages.

PRODUCT GROUP	INTENDED USE
Straight Abutments	It is the superstructure part that supports fixed partial dentures manufacture on a straight implant. It is used in single member or bridge cemented restorations. Cement retained abutments have a different gingival height of 1-5 mm, diameters of 3.5, 4.5, 6 mm depending on the platform diameters.
Healing Caps	Following the second surgery of the gingiva in two-stage surgical procedures, and after the placement of the implant in single-stage surgeries, it is screwed into the implant body and protects the internal structure of the implant. It is not used to support a prosthetic superstructure. It is used for transgingival healing and shaping of soft tissue during the healing process of soft tissue. There are two different designs for healing caps in dental implant systems. These are manufactured to be compatible with tissue level and bone level implants.

Abutment Screws	Connects and fixes the abutment and implant body.

Dental Implant

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE DEVICE	REFERENC E DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Technological Characteristics	Proimtech Dental Body Implant (K231100)	Straumann Bone Level Tapered Implants (K140878)	Straumann® Bone Level Tapered Implants (K140878)	Straumann® BLX Implant System (K173961)	BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants (K212533)	Straumann Dental Implant System SLActive and Roxolid Product Families (K130222)
Product Code	DZE	DZE	DZE	DZE	DZE	DZE

Indications for Use	Indications for use Bilimplant® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases	Straumann® dental implants are indicated for oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. Straumann dental implants can also be used for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments). In cases of fully edentulous patients, 4 or more implants must be used in immediately loaded cases.	Straumann BLX Implants are suitable for endosteal implantation in the upper and 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 achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components.	Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple-tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.	Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches for the functional and aesthetic oral rehabilitation of edentulous and partially dentate patients. Straumann® Dental implants are also indicated for immediate or early implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).

Material	Grade 4 commercially pure titanium conforming with ISO 5832-2	Grade 4 commercially pure titanium conforming with ISO 5832-2	Commercially pure grade 4 titanium & Titaniun-13Zirconium alloy (Roxolid®)	Titanium -13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)	Titanium-13 Zirconium alloy (Roxolid®)
Surface Treatment	Sand blasted Large grit Acid etched (SLA)	Sand blasted Large grit Acid etched (SLA)	SLA, SLActive	Hydrophilic SLActive®	Hydrophilic SLActive® and SLA®	SLA, SLActive
Design						
Single Use Only	Yes	Yes	Yes	Yes	Yes	Yes

Transfer piece	Fixture-mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Snap fit mount Loxim™ transfer piece, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Fixture-mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Fixture-mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Fixture-mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.	Fixture- mount transfer part, intended to support the implant while in the primary package, to aid in the removal of the implant from the primary package, and to aid in placement of the implant into the osteotomy site.
Diameter (mm)	3.7, 4.1, 4.8, 5.5,	3.3, 4.1, 4.8	4.1, 4.8	Ø 4.5, Ø5.5, Ø6.5 mm	Ø5.0, Ø5.5, Ø6.5 mm	Ø4.1, Ø4.8 mm

Length (mm)	8, 10, 12, 14	8, 10, 12, 14	8, 10, 12, 14	6 to 18 mm	Ø5.0 mm: 18 mm Ø5.5 and 6.5 mm: 14 and 16mm	6, 8, 10, 12 mm
Sterilization	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)	Sterile (Gamma irradiation)

Substantial Equivalence Discussion

Similarities
The device has the same characteristics compared to the reference devices in the following aspects. Indication for Use, Design, Material, Surface Treatment, Disposable, Transfer Part and Sterilization.

Difference
The diameter and length dimensions of the device in question are slightly different from the reference device. However, as a result of the tests conducted, it was decided that there was no significant difference in product performance and that this difference did not affect substantial equivalence.
Reference to four implants for fully edentulous patients is not necessary because the subject device is intended for fully edentulous patients, it is not intended for full-arch restorations.

Discussion
On the basis of the above discussion, it is concluded that the device in question is substantially equivalent to the reference device.

Abutment

Technological Characteristics	SUBJECT DEVICE	REFERENCE DEVİCE
	Proimtech Abutment	Nucleoss Abutment System (K160850)
Product Code	NHA	NHA
Indications for Use	Bilimplant Abutments and Prosthetic parts are intended for use with Bilimplant Dental Implants in the maxillary and / or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.	Nucleoss Abutments and Prosthetic parts are intended for use with Nucleoss Tpure Dental Implants in the maxillary and/or mandibular arches to provide support for crowns, bridges or overdenture for edentulous or partially edentulous patients.
Abutment Design	Straight: Internal quadrilateral connection for single or multiple cement-retained restorations.	Straight: For single or multiple cement retained restorations Internal hex connection.

Material	Titanium alloy	Titanium alloy

Abutment Platform Diameter (mm)	Straight: 3.5, 4.5, 5, 6	Straight: 4.2, 5.0 6.0
Abutment Platform Heights (mm)	Straight: 5.5, 7	Straight: 1.0, 2.0, 3.0, 5.0
Gingival Height	1, 2, 3, 4 and 5 mm	1, 1.5, 2, 3, 4, 4.5 and 5 mm
Single Use Only	Yes	Yes
Sterilization	Provided non- sterile	Provided non-sterile
Recommended Sterilization Method	Autoclave Moist Heat or Steam	Autoclave Moist Heat or Steam

Design		

Substantial Equivalence Discussion
Similarities The device in question has the same characteristics compared to the reference device in the following aspects. Abutment Design, Material, Single use and Sterilization. **Difference** The connection type of the device in question is Four Corner Connection Type. Abutment Platform Diameter and Abutment Platform Heights are slightly different from the reference device. However, as a result of the tests, it was decided that there was no significant difference in product performance and that this difference did not affect the substantial equivalence. **Discussion** On the basis of the above discussion, it is concluded that the device in question is substantially equivalent to the reference device.

Healing Cap

	SUBJECT DEVICE	REFERENCE DEVİCE	REFERENCE DEVİCE
Product Code	NHA	NHA	NHA
Device Name	Proimtech Healing Cap	Implantium Abutments (Healing Abutment)	CAMLOG Dental Implant Abutments, Healing Caps, and Accessories
Manufacturer	PROIMTECH SAGLIK URUNLERI ANONIM SIRKETI	Dentium Co., Ltd.	Altatec GmbH
510(k) Number	K231100	K052957	K051636
Indication for use	Bilimplant Abutments and Prosthetic parts are intended for use with Bilimplant Dental Implants in the maxillary and / or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.	Implantium Prosthetics is intended for use as an aid in prosthetic rehabilitation.	CAMILOG (Cylindrical, Wide Body. Bottleneck) displace the gingiva from the space above the CAMILOG implant or bar abutment during the CAMLOG implant healing time and serve for proper gingiva shaping.
Materials	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Titanium Alloy Ti-6Al-4V ELI

Connection type	Internal	Internal	Internal
Sterilization	Non-sterile	Non-sterile	Sterile
Recommended Sterilization Method	Autoclave Moist Heat or Steam	Autoclave Moist Heat or Steam	Gamma Irradiation
Single Use Only	Yes	Yes	Yes
Diameter	3.5, 4.5, 4.8, 5, 5.4, 6.5	4.04 / 4.10 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 5.50 / 5.54 / 5.64 / 5.75 6.50 / 6.54 / 6.64 / 6.75 / 7.64 / 8.64 / 9.64	3.3. 3.8, 4.3. 5 and 6mm Cylindrical
Length	4.70, 5.10, 5.40, 6.20, 6.50, 6.90, 7.20, 7.50, 8, 8.20, 8.40, 8.50, 9, 9.40, 9.70, 10, 10.20, 10.40, 10.50, 11, 11.20, 11.40, 11.50, 11.70, 12, 12.50	8.70 / 10.91 / 10.93 / 11.04 / 11.15 / 12.41 / 12.44 / 12.55 / 12.65 / 12.66 14.42 / 14.44 / 14.55 / 14.66	2, 4 and 6mm
Gingival Height	1, 2, 2.5, 3, 4, 5, and 6 mm	3, 4, 5 and 7 mm	2, 4 and 6 mm
Design			

Substantial Equivalence Discussion

Similarities

The device in question has the same characteristics compared to the reference device in the following aspects. Design, Material, Connection Type, Single use and Sterilization.

Difference

The diameter and length dimensions of the device in question are slightly different from the reference device. However, there is no significant difference in product performance and this difference does not affect the substantial equivalence.

Discussion

On the basis of the above discussion, it is concluded that the device in question is substantially equivalent to the reference device.

Abutment Screw

	SUBJECT DEVICE	REFERENCE DEVİCE
Product Code	NHA	NHA
Device Name	Proimtech Abutment Screw	Abutment Screw
Manufacturer	PROIMTECH SAGLIK URUNLERI ANONIM SIRKETI	MegaGen Implant Co., Ltd.
510(k) Number	K231100	K182448
Indication for use	Bilimplant Abutments and Prosthetic parts are intended for use with Bilimplant Dental Implants in the maxillary and / or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.	Abutment Screw is used for securing the abutment to the endosseous implant.
Materials	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Connection Interface	External Conical Connection	Internal Conical Connection
Sterilization	Non-sterile	Non-sterile
Recommended Sterilization Method	Autoclave Moist Heat or Steam	Autoclave Moist Heat or Steam
Single Use Only	Yes	Yes
Surface Treatment	Machined, Anodizing	Machined
Diameter	2, 2.2, 2.3	2.2
Length	4.50, 5.50, 7.90, 8.10	7.9
Design		

Substantial Equivalence Discussion

Similarities

The device in question has the same characteristics compared to the reference device in the following aspects. Indication for Use, Design, Material, Surface Treatment, Single use and Sterilization.

Difference

The diameter, length dimensions and connection interface of the device in question are slightly different from the reference device. However, there is no significant difference in product performance and this difference does not affect the substantial equivalence.

Discussion

On the basis of the above discussion, it is concluded that the device in question is substantially equivalent to the reference device.

PERFORMANCE DATA

The subject device was evaluated and tested as recommended in the FDA guidance documents Root Form Endosseous Dental Implants and Endosseous Dental Implant Abutments (issued May 12,2004), Use of International Standard ISO 10993-1, "Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process" (issued September 4,2020), Reprocessing Medical Devices in Health Care settings: Validation Methods and Labelling (issued March 17, 2015), Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile (issued January 21,2016), and Pyrogen and Endotoxins Testing: Questions and Answer (issued June 2012).

Non-clinical data presented to demonstrate substantial equivalence include: Gamma sterilization validation for device implants and valve screws according to ISO 11137-1 and ISO 11137-2; Bacterial endotoxin (BET) testing, including Limulus amebocyte lysate (LAL) testing according to USP-43- NF38: 2020 <85>, in accordance with ASTM F1980 and shelf life validation through packaging stability in accordance with ISO 11601; moist heat sterilization in accordance with ISO 17665-1 and ISO TS 17665-2 (to be performed by the end user); biocompatibility testing in accordance with ISO 10993-5 and ISO 10993-12.

The endosseous threaded surface of the subject device implants is grit-blasted with non-resorbable aluminum oxide (Al2O3) particles; this surface was validated by scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS) characterization.
Bacterial endotoxins in the subject devices provided sterile to the end user will be monitored and BET level meets level of ≤ 20 EU/device.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject devices are broadly equivalent in indications and design principles to the primary predecessor and reference devices listed above. At the beginning of this summary is a table comparing the Indications for Use and tables comparing the technological characteristics of the subject device, the primary precursor device and the reference devices.

The Indications for Use Statement (IFUS) of the subject device is substantially equivalent to that of the primary precursor device K140878 510k and the reference devices K173961, K212553, K130222, K160850, K182448, K052957, K051636 510k. Minor differences in the language of the IFUS do not affect its intended use as an endosseous dental implant and dental implant abutments to support a prosthesis to restore masticatory function.

There are minor differences between the IFUS of the device in question and the primary predicate device. These minor differences do not raise new safety or efficacy questions as the IFUS states equivalent intended use.

CONCLUSION

The subject device, the primary predicate device, and the additional predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device, the primary predicate device, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.