



medentis medical GmbH  
% Floyd Larson  
President  
PaxMed International, LLC  
12264 El Camino Real, Suite 400  
San Diego, California 92130

September 5, 2024

Re: K231566

Trade/Device Name: ICX-Implant System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: August 7, 2024  
Received: August 8, 2024

Dear Floyd Larson:

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

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

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

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

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

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

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

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

## Indications for Use

510(k) Number (if known)

Device Name

ICX-Implant System

Indications for Use (Describe)

ICX-Implant System is indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. ICX- Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7.0 mm are indicated for delayed loading only.

ICX-Implant System CAD CAM abutments are intended for use with dental implants as a support for single unit or multiple unit prostheses in the maxilla or mandible of a partially or fully edentulous patient. All digitally designed abutments for use with ICX-Implant System CAD CAM abutments are intended to be manufactured at a medentis medical GmbH validated milling center.

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**  
**medentis medical GmbH**  
**ICX-Implant System**

September 5, 2024

**ADMINISTRATIVE INFORMATION**

Manufacturer Name	medentis medical GmbH Walporzheimer Strasse 48-52 Bad Neuenahr-Ahrweiler, 53474, Germany Telephone +49 2641 9110-171 Fax +49 2641 9110-120
Official Contact	Alexander Scholz, CEO
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: flarson@paxmed.com; kthomas@paxmed.com

**DEVICE NAME AND CLASSIFICATION**

Trade/Proprietary Name	ICX-Implant System
Common Names	Endosseous dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1B (Dental and ENT Devices)

**PREDICATE DEVICE INFORMATION**

Primary Predicate Device  
K130222, Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann USA,

Reference Devices

K133510, Neodent Implant System, JJGC Indústria e Comércio de Materiais Dentários SA  
K163194, Neodent Implant System - GM Line, JJGC Indústria e Comércio de Materiais Dentários SA  
K222288, DESS Dental Smart Solutions, Terrats Medical SL  
K193096, S.I.N. Dental Implant System, S.I.N. –Sistema de Implante Nacional S.A.  
K213063, TLX SRAs and TLX Gold Abutments, Institut Straumann AG

K092035, Bicon Implants with a 2.5 mm Internal Connection, Bicon, L.L.C.  
K140440, Noris Medical Dental Implants System, Noris Medical, Ltd.  
K193046, Straumann® Retentive System – Novaloc TiN Abutments, Institut Straumann AG  
K153779, Abutment for Bridges, Altatec GmbH  
K203252, Multi-unit Abutments for CONELOG®, BioHorizons Implant Systems, Inc.  
K191123, Multi-unit Abutments, Medentika GmbH, Straumann USA, LLC  
K170131, TAV Medical Dental Implant System, Tav Medical Ltd.  
K233208, NobelProcera® Titanium ASC Abutment, Nobel Biocare AB  
K212108, Dynamic TiBase, Talladium España, SL

#### INDICATIONS FOR USE STATEMENT

ICX Implant Systems is indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. ICX Implant Systems is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7.0 mm are indicated for delayed loading only.

ICX Implant Systems CAD-CAM abutments are intended for use with dental implants as a support for single-unit or multiple-unit prostheses in the maxilla or mandible of a partially or fully edentulous patient. All digitally designed abutments for use with ICX Implant Systems CAD-CAM abutments are intended to be manufactured at a medentis medical GmbH validated milling center.










#### SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for an endosseous dental implant and abutment system, ICX-Implant System, from medentis medical GmbH. The ICX-Implant System includes a range of endosseous dental implants and prosthetic components. All implants have a self-tapping apical thread with a tapered body and root-form designs with an internal hex implant/abutment connection. The implant body surface is blasted and acid-etched.

Abutments are available in multiple designs, including straight and angled abutments intended for single tooth and multi-unit restorations.

Table 1. *ICX-Implant System Overview* contains an overview of the system images and features.

**Table 1. ICX-Implant System Overview**

Implants									
Implant Line	ICX-Premium		ICX-Diamond Premium		ICX-Active Master		ICX-Diamond Active Master		ICX-Active Liquid
<b>Image</b> <i>Not to Scale</i>									
<b>Placement</b>	Bone Level	Tissue Level	Bone Level	Tissue Level	Bone Level	Tissue Level	Bone Level	Tissue Level	Bone Level
<b>Collar Design</b>	Micro-threaded collar		Micro-threaded collar		Threaded to top		Threaded to top		Threaded to top
<b>Packaging</b>	Air		Saline		Air		Saline		Saline
<b>Material</b>	Unalloyed titanium		Unalloyed titanium		Unalloyed titanium		Unalloyed titanium		Unalloyed titanium
<b>Body Ø (mm)</b>	3.43 – 4.8		3.43 – 4.8		3.43 – 4.8		3.43 – 4.8		3.43 – 4.8
<b>Platform Ø (mm)</b>	3.3 – 3.7		3.3 – 3.7		3.3 – 3.7	3.3	3.3 – 3.7	3.3	3.3 – 3.7
<b>Endosseous Lengths* (mm)</b>	8 – 15	5 – 12.5	8 – 15	5 – 12.5	8 – 15		8 – 15		8 – 15
*Tissue Level implants have a 1.7 mm gingival collar (2.7 mm for 5 mm length). Overall length of Tissue Level implants is 1.7 mm (2.7 mm) greater than shown.									
Healing Components, Abutments, Screws									
<b>Healing Components, Abutments</b>	<ul style="list-style-type: none"> <li>• ICX-Cover Screw</li> <li>• ICX-Healing Cap</li> <li>• ICX-Titanium Abutment</li> <li>• ICX-Titanium Aesthetic Abutment</li> <li>• ICX-Massive Abutment</li> <li>• ICX-Universal Abutment</li> <li>• ICX-Bar System Abutment</li> <li>• ICX-Maximus Abutment</li> <li>• ICX-UCLA Abutment</li> <li>• ICX-Multi Abutment</li> <li>• ICX-Adhesive Base Abutment (CAD/CAM)</li> </ul>				<b>Screws</b>	<ul style="list-style-type: none"> <li>• ICX-3.3 Connection Screw</li> <li>• ICX-3.3 Multi Connection Screw</li> <li>• ICX Connection Screw Type A</li> <li>• ICX Connection Screw Type B</li> <li>• ICX Multi Connection Screw</li> <li>• ICX Multi Prosthetics Screw</li> <li>• ICX Maximus Connection Screw</li> </ul>			

**MATERIAL COMPOSITION**

All subject device dental implants are manufactured from cold worked unalloyed titanium Grade 4 conforming to ASTM F67 *Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)* and Grade 4B conforming to ISO 5832-2 *Implants for surgery – Metallic materials – Part 2: Unalloyed titanium*. The threaded endosseous surface of the implant is blasted and acid-etched from the implant collar to the apex.

Subject device healing components, (cover screws and healing caps) are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* or PEEK-Classix™ by Invibio.

Subject device abutments are manufactured from titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for*

*Surgical Implant Applications (UNS R56401)*, cobalt-chromium 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)*, or gold alloy (Ceramicor). The ICX-Multi Interim Abutment is manufactured from PEEK-Classix™ by Invibio. The burn-out sleeve packaged with the ICX-UCLA Abutments and ICX-CoCr Abutment is manufactured from polyoxymethylene (POM). The retention rings that are used with the denture housing are manufactured from nylon (Grilamid).

The material for manufacture of zirconia superstructures for Adhesive Base Abutments is yttria-stabilized zirconia (Y-TZP) from Dental Direkt GmbH (K150196, K142987, K170885, K183569). The cement recommended in labeling for bonding of superstructures is Panavia F 2.0 cement by Kuraray Medical, Inc, cleared under K032455.

The subject device screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

#### SURFACE TREATMENTS

The threaded endosseous surface of the subject device implants is grit-blasted and acid-etched from the implant collar to the apex. The subject device Maximus abutments have a titanium nitride (TiN) coating applied to the coronal end of the abutment. Some subject device abutments are anodized for color coding purposes.

#### PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

- validation of gamma irradiation sterilization for subject devices provided sterile to the end user to a sterility assurance level of  $10^{-6}$  by selecting and substantiating a 25 kGy dose using method VDmax<sub>25</sub>, 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*;
- bacterial endotoxin testing including *Limulus* amoebocyte lysate (LAL) test according to ANSI/AAMI ST72 *Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing* on samples from sterilized product to demonstrate all sterile product meets a limit of  $\leq 20$  EU/device;
- validation of the recommended moist heat sterilization cycle 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/TR 17665-2 *Sterilization of health care products – Moist heat - Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1*;
- shelf life testing, including testing of samples after 5 years of real time aging according to ASTM F1929 *Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration* and F88/F88M *Standard Test Method for Seal Strength of Flexible Barrier Materials*, and sterility testing of product;
- biocompatibility testing of samples representing all subject device material (including zirconia from Dental Direkt GmbH) and manufacturing processes according to ISO 10993-5 *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, including ;*

- characterization of the implant acid-etched surface included scanning electron microscopy (SEM) and surface chemistry analysis;
- Characterization of TiN coated and anodized surfaces;
- Characterization of super hydrophilicity by contact angle measurements before and after aging;
- mechanical testing according to ISO 14801 *Dentistry – Implants – Dynamic loading test for endosseous dental implants*;
- analysis of the surface area and initial bone to implant contact area of short implants and comparison with a reference device;
- MR compatibility testing to support labeling as MR Conditional

No clinical data were included in this submission.

#### EQUIVALENCE TO MARKETED DEVICES

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

##### *Substantial Equivalence of Indication for Use Statement (IFUS)*

The Indications for Use Statement (IFUS) of the subject device implants compared to those of the primary predicate and reference devices are detailed below in *Table of Substantial Equivalence – Indications for Use Statement*. The IFUS for the subject device is substantially equivalent to that of the primary predicate K130222 and reference device K133510, K163194, K222288, K193096, K213063, and K092035. There is a difference in terminology used, however, the intended use is the same. All implants and abutments are intended to be used with dental implants for support for prosthetic restoration for edentulous or partially edentulous patients. Delayed loading indications have been added for the short implants (endosseous length less than 7 mm). The digitally designed abutments are to be sent to a validated milling center for manufacture similar to reference devices K163194, K222288 and K193096.

##### *Substantial Equivalence of Technological Characteristics - Implants*

The subject device implant offers two (2) implant placement types: bone level and tissue level, similar to the primary predicate K130222. The subject device implant has an internal connection similar to the primary predicate K130222, however, the subject device has an internal hex and primary predicate K130222 has an internal octagon. Any risks that may be associated with different implant placement levels and implant/abutment connection, have been mitigated by mechanical testing

The subject device implants have body diameters ranging from 3.43 mm to 4.8 mm. The smallest subject device body diameter is similar to that of the primary predicate K130222.. The largest and smallest subject device diameters are similar to those of primary predicate K130222.

The subject device implant length of 8 mm to 15 mm is similar to the primary predicate K130222 (implants with 8 mm to 16 mm length) and the reference device K133510 (implants with 9 mm to 19 lengths).

The subject device includes short implants (defined as implants with endosseous length less than 7 mm) with endosseous lengths of 5 mm and 6.5 mm. The short implants are available only with one implant line, the ICX-Premium TL and ICX-Diamond Premium TL tissue level implant. Both implant lengths are offered with a 4.8 mm implant diameter. These dimensions are similar to those of the reference device K092035 with implants having a 5 mm length and a 4.0 mm implant diameter. A surface area evaluation and bone to implant contact computation have been conducted comparing the short subject device implants to the reference device.

The subject device implants are manufactured from the same material (unalloyed titanium Grade 4) and have the same endosseous surface treatment (grit-blasted and acid-etched) as the reference device K133510. Any risks that may be associated with the surface treatment have been mitigated by biocompatibility evaluation and surface treatment evaluation.

The subject device implants are provided sterile to the user, for single patient, single use, the same as the primary predicate and reference devices.

#### *Substantial Equivalence of Technological Characteristics – Prosthetic Components*

The technological characteristics of the subject device abutments are compared to the reference devices, shown below in Tables 2-10 *Table of Substantial Equivalence – Technological Characteristics*. **Table 3. Table of Substantial Equivalence – Technological Characteristics.** The primary predicate K130222 is not being used to evaluate these characteristics, as it is included only for evaluation of the implants. The reference device K092035 is not being used to evaluate these characteristics, as it is included only for evaluation of surface area of short implants.

The subject device healing component offers diameters that range from 2.6 mm to 8.0 mm with a threaded connection. The range of diameters is similar to those of the reference devices. The subject device healing components are used only for healing purposes and are placed out of occlusion, therefore mechanical strength is not a risk that requires mitigation.

The subject device abutments are provided in diameters that range from 3.7 mm to 6.5 mm with a hex connection and angulation of 0°, 15°, and 25°. The diameters, connections, and angulations are similar to those of the reference device abutments.

The subject device overdenture abutments are provided in diameters that range from 4.5 mm to 7.0 mm with a hex connection. The subject device diameters are similar to those of the reference device K133510. The subject device overdenture abutments are not intended for angulation or angle correction, and therefore mechanical strength is not a risk requiring mitigation.

The subject device UCLA abutments are provided in diameters that range from 4.4 mm to 5.0 mm with a hex and non-hex connection. The subject device diameters are similar to those of the reference device K193096. The subject device UCLA abutments are two-part cast-on abutments consisting of a cobalt-chromium alloy or gold base and a polyoxymethylene (POM) burn-out sleeve. The POM burn-out sleeve can be cast in cobalt-chromium alloy or nickel-chromium alloy. This is similar to those of the reference device K193096 and K213063. The subject device UCLA abutments are not intended for angulation or angle correction.

The subject device Multi abutments are provided in diameter of 4.8 mm with a hex, non-hex, and threaded connection and angulation of 0°, 17° and 30°. The subject device diameters, connection, and

angulation are similar to those of the reference device K222288. The subject device abutment does not have a diameter smaller or larger, or an angulation greater than those of the reference device K222288.

The subject device base abutments are provided in diameters ranging from 4.4 mm to 5.1 mm with a hex and non-hex connection and angulation up to 15° using a base manufactured from titanium alloy or Co-Cr alloy and a zirconia superstructure. The subject device diameters, connection, angulation, and material are similar to those of the reference devices K163194 and K222288. The subject device abutment does not have a diameter smaller or larger, a greater angulation, or material different than those of the reference device K136194 and K222288. The two-pieces of the Ti Base abutment which compose the final abutment consist of the pre-manufactured titanium base component composed of titanium alloy and the CAD/CAM patient matched superstructure composed of zirconia.

All subject device abutments (healing components, abutments, and ball abutments) are made from titanium alloy (ASTM F136), cobalt-chromium alloy (ASTM F1537), gold alloy (Ceramicor), and PEEK-CLASSIX™, which is same as the reference devices.

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
- has similar packaging and is sterilized using the same materials and processes.

The basis for the belief of medentis medical GmbH that the subject device is substantially equivalent to the predicate devices is summarized in the following tables, Table 2 Table of Substantial Equivalence – Indications for Use Statement and Tables 3-11 Table of substantial Equivalence – Technological Characteristics.

**Table 2. Table of Substantial Equivalence – Indications for Use Statement**

Subject device	Indications for Use Statement
<p>ICX-Implant System medentis medical GmbH.</p>	<p>ICX Implant Systems is indicated for use in partially or fully edentulous patients to support maxillary and mandibular single-unit, multiple-unit, and overdenture dental restorations. ICX Implant Systems is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7.0 mm are indicated for delayed loading only.</p> <p>ICX Implant Systems CAD-CAM abutments are intended for use with dental implants as a support for single-unit or multiple-unit prostheses in the maxilla or mandible of a partially or fully edentulous patient. All digitally designed abutments for use with ICX Implant Systems CAD-CAM abutments are intended to be manufactured at a medentis medical GmbH validated milling center.</p>
Primary predicate device	
<p>K130222 Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann USA, Limited Liability Company</p>	<p>Straumann® Dental implants are indicated for oral endosteal implantation in the upper and lower jaw arches and 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.</p> <p>The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments).</p>
Reference devices	
<p>K133510 Neodent Implant System JJGC Indústria e Comércio de Materiais Dentários SA</p>	<p>The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Multiple tooth applications may be rigidly splinted.</p>
<p>K163194 Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA</p>	<p>Indications for Use for GM implants and conventional abutments: The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.</p> <p>Indications for Use for GM Titanium Base abutments: Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.</p> <p>Indications for Use for GM Pro Peek Abutments: The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability</p>

	<b>Indications for Use Statement</b>
<p>K222288 DESS Dental Smart Solutions Terrats Medical SL</p>	<p>DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.</p> <p>All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.</p> <p><i>For complete Indications for Use statement on OEM Compatibility see 510(k) Summary for K222288 in Section 12</i></p>
<p>K193096 S.I.N. Dental Implant System S.I.N. –Sistema de Implante Nacional S.A.</p>	<p>S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. All digitally-designed custom abutments for use with Interface CAD-CAM abutments are to be sent to a S.I.N.-validated milling center for manufacture</p>
<p>K213063 TLX SRAs and TLX Gold Abutments Institut Straumann AG</p>	<p>TLX SRAs Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges, or full-arch prostheses.</p> <p>TLX Gold Abutments Straumann® abutments are indicated to be placed into Straumann® dental implants to provide a support structure for the functional and esthetic oral rehabilitation of edentulous or partially edentulous patients with crowns, bridges or full-arch prostheses. Copings are indirectly connected to the endosseous dental implant and are indicated for use as an aid in prosthetic rehabilitations.</p>
<p>K092035 Bicon Implants with 2.5mm Internal Connection Bicon, L.L.C.</p>	<p>The Bicon implant is designed for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement.</p>

**Table 3. Table of Substantial Equivalence – Technological Characteristics  
Implants**

Feature	Subject Device		Primary Predicate		Reference Device	Reference Device
	ICX-Implant System medentis medical GmbH.		K130222 Straumann® Dental Implant System SLActive and Roxolid Product Families		K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K092035 Bicon Implants with 2.5mm Internal Connection Bicon ,L.L.C.
Product Code	DZE, NHA		DZE & NHA		DZE & NHA	DZE
Reason for Predicate/ Reference Device	n/a		Tissue and bone level implants		Implant material and surface treatment, ball abutment	Surface area comparison
Implant Placement	Bone Level	Tissue Level	Bone level	Tissue Level	Bone level	Bone Level
Prosthetic Interface Connection	Internal Hex		Internal octagon		External hex	Morse Taper
Body Diameter, mm	3.43, 3.9, 4.25, 4.8		2.9, 3.3, 4.1, 4.8		Titamax Smart – 3.3, 3.75, 4.0, 4.5, 5.0 Titamax Smart EX - 3.75, 4.0	4.0, 4.5 <i>From marketing material, not stated in 510(k) Summary</i>
Platform Diameter, mm	3.3, 3.7		Same as body	3.5, 4.8	3.3, 4.5	3.5
Endosseous Lengths, mm	8, 10, 12.5, 15 (no 15 mm length for 3.3 Ø)	5, 6.5, 8, 10, 12.5 (5 & 6.5 mm only for 4.8 Ø)	8, 10, 12, 14, 16, 18 (no 8 mm for 2.9 Ø)	4, 6, 8, 10, 12, 14 (no 4, 6, 8 mm for 3.3 Ø)	Titamax Smart - 9, 11, 13, 15, 17 Titamax Smart EX - 9, 11, 13, 15, 17, 19	5, 8, 11 (no 5 mm for 4 Ø)
Implant Material	Unalloyed titanium		Zirconium alloy (Roxolid), 15% zirconium and 85% titanium		Unalloyed titanium	Titanium alloy (Ti6Al-4V)
Implant Endosseous Surface	Aluminum Oxide (Al <sub>2</sub> O <sub>3</sub> ) Blasted, Acid Etched		Large grit sandblasted, acid-etched		Grit blasted, acid etched	Grit blasted, acid etched, and hydroxylapatite
Stored	Air and Saline		Air and Saline		Air and saline	Air

**Table 4. Table of Substantial Equivalence – Technological Characteristics  
Cover Screws**

Feature	Subject Device	Reference Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K163194 Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA	K193096 S.I.N. Dental Implant System S.I.N. –Sistema de Implante Nacional S.A.
<b>Coronal Ø, mm</b>	2.6-3.7	Not stated	4.5, 6	3.65
<b>Connection</b>	Threaded / taper	Hex	Threaded / taper	Threaded / taper
<b>Gingival Height, mm</b>	0 – 2	Not stated	0.8-5.5	2-4
<b>Material</b>	Titanium alloy	Titanium alloy	Titanium alloy	Titanium Alloy
<b>Surface treatment</b>	Anodized, None	None	Anodized, None	Anodized, None
<b>Used with implants</b>	BL, TL	BL	BL	BL
<b>How Provided</b>				
<b>Sterility</b>	Sterile	Non-sterile	Sterile	Sterile
<b>Usage</b>	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 5. Table of Substantial Equivalence – Technological Characteristics  
Healing Caps**

Feature	Subject Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K163194 Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA	K222288 DESS Dental Smart Solutions Terrats Medical SL
<b>Coronal Ø, mm</b>	3.9/4.7 – 8.0	3.3 – 6.5	3.0 – 7.7
<b>Gingival Height, mm</b>	1.0 – 6.0 (PEEK customizable 1.24 – 10.46)	0.8 – 5.5	Not stated
<b>Connection</b>	Threaded, hex	Threaded, hex	Threaded
<b>Material</b>	Titanium alloy, PEEK	Titanium alloy, PEEK	Titanium Alloy
<b>Surface treatment</b>	Anodized, None	Anodized, None	None
<b>Used with implants</b>	BL	BL	BL
<b>How Provided</b>			
<b>Sterility</b>	Non-sterile	Non-sterile	Non-sterile
<b>Usage</b>	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 6. Table of Substantial Equivalence – Technological Characteristics  
ICX-Titanium Abutment, ICX-Titanium Aesthetic Abutment**

Feature	Subject Device	Reference Device	Reference Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K140440 Noris Medical Dental Implants System Noris Medical, Ltd.	K163194 Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA	K222288 DESS Dental Smart Solutions Terrats Medical SL	K233208 NobelProcera® Titanium ASC Abutment Nobel Biocare AB
<b>Prosthetic Platform Ø, mm</b>	3.7 – 6.5	Not stated	3.3-4.8	4,5 – 6.5	3.13 – 6.0
<b>Gingival Height for BL implants, mm</b>	0.3 – 5.6	0.5 – 4.0	0.8-5.5	0.4 – 6.0	0.3 min.
<b>Gingival Height for TL implants, mm</b>	N/A (GH is in implant)			N/A	N/A
<b>Angulation</b>	0°, 15°, 25°	0°, 17°, 30°	up to 15°	0°, 17°, 30°	0° to 30°
<b>Connection</b>	Engaging, Non-engaging	Engaging, Non-engaging	Engaging, Non-engaging	Engaging, Non-engaging	Engaging
<b>Restoration retention</b>	Cement	Cement	Cement	Cement	Cement
<b>Material</b>	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
<b>Surface treatment</b>	Anodized, None	Anodized, None		Anodized, None	Anodized, None
<b>Used with implants</b>	BL, TL	BL	BL	BL, TL	BL
<b>How Provided</b>					
<b>Sterility</b>	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
<b>Usage</b>	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 7. Table of Substantial Equivalence – Technological Characteristics  
ICX-Massive Abutment, ICX-Universal Abutment**

Feature	Subject Device	Reference Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K163194 Neodent Implant System - GM Line JJGC Indústria e Comércio de Materiais Dentários SA	K222288 DESS Dental Smart Solutions Terrats Medical SL
<b>Prosthetic Platform Ø, mm</b>	N/A	3.3. – 5.0	3.3-4.8	3.5-6.5
<b>Gingival Height, mm</b>	1.14 – 2.8	2-5	0.8-5.5	
<b>Post height, mm</b>	4.0 - 11.	Not stated	Not stated	
<b>Angulation</b>	None (0°)	0°, 17°, 30°	up to 15°	0°
<b>Connection</b>	Non-engaging	Engaging	Engaging	Engaging, Non-engaging
<b>Restoration retention</b>	Cement	Cement	Cement	Cement
<b>Used with implants</b>	BL, TL	BL	BL	BL
<b>Material</b>	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
<b>Surface Treatment</b>	Anodized, None		None	
<b>How Provided</b>				
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 8. Table of Substantial Equivalence – Technological Characteristics  
ICX Maximus Abutment (Overdenture Attachment System), ICX-Bar System Abutment**

Feature	Subject Device	Reference Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K193046 Straumann® Retentive System – Novaloc TiN Abutments Institut Straumann AG	K133510 Neodent Implant System JJGC Industria e Comercio de Materiais Dentarios SA	K153779 Abutments for Bridges Altatec GmbH
<b>Gingival Height, mm</b>	1 – 5	1 – 6	2-5	0.4 – 2.2
<b>Connection</b>	Engaging, non-engaging	Non-engaging	Non-engaging	Non-engaging
<b>Material</b>	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
<b>Surface Treatment</b>	TiN coating	TiN coating	TiN coating	None
<b>Insert</b>	Nylon Inserts	Nylon Inserts	Nylon Inserts	N/A
<b>Used with implants</b>	BL, TL	BL, TL	BL	BL
<b>How Provided</b>				
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 9. Table of Substantial Equivalence – Technological Characteristics  
ICX-UCLA Abutments**

Feature	Subject Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH	K193096 S.I.N. Dental Implant System S.I.N. –Sistema de Implante Nacional S.A.	K213063 Straumann TLX SRAs Straumann USA, LLC
Prosthetic Platform Ø, mm	4.4-5.0	3.8, 4.5	4.6
Gingival Height, mm	0.5	0.5, 1	3.5
Connection	Hex, Non-hex	Hex	TorcFit
Material	Co-Cr alloy, Gold (Ceramicor) alloy	Co-Cr alloy	Gold (Ceramicor) alloy
Angulation	Straight only	Straight only	Straight only
Used with implants	BL, TL	BL	TL
How Provided			
Sterility	Non-sterile	Non-sterile	Sterile
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 10. Table of Substantial Equivalence – Technological Characteristics  
ICX-Multi Abutments**

Feature	Subject Device		Reference Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K222288 DESS Dental Smart Solutions Terrats Medical SL	K203252 Multi-unit Abutments for CONELOG® BioHorizons Implant Systems, Inc.	K191123 Medentika Multi-unit Abutments Medentika GmbH Straumann USA, LLC	K233208 NobelProcera® Titanium ASC Abutment Nobel Biocare AB
<b>Prosthetic Platform Ø, mm</b>	4.8	3.0 – 5.0	4.8	4.5 – 6.5	3.13 – 6.0
<b>Gingival Height, mm</b>	0.4 – 4.5	Not stated	2.0 – 4.0	0.6 – 5.5	0.3 min.
<b>Angulation</b>	0°, 17°, 30°	0°, 17°, 30°	0°, 17°, 30°	0°, 17°, 30°	0° to 30°
<b>Connection</b>	Engaging, Non-engaging	Engaging, Non-engaging	Engaging	Engaging, Non-engaging	Engaging
<b>Restoration retention</b>	Screw	Screw	Screw	Screw	Screw
<b>Material, MUA</b>	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
<b>Materials, Prosthetic components</b>	Titanium Alloy PEEK CoCr Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy Gold Cobalt Chromium	N/A
<b>Used with implants</b>	BL, TL	BL	BL	BL, TL	BL
<b>How Provided</b>					
<b>Sterility</b>	Non-sterile	Non-sterile	Non-sterile	Sterile	Sterile
<b>Usage</b>	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use	Single patient, single-use

**Table 11. Table of Substantial Equivalence – Technological Characteristics  
ICX-Adhesive Base Abutments (CAD-CAM)**

Feature	Subject Device	Reference Device	Reference Device
	K231566 ICX-Implant System medentis medical GmbH.	K222288 DESS Dental Smart Solutions Terrats Medical SL	K212108 Dynamic TiBase Talladium España, SL
Prosthetic Platform Ø, mm	4.4	3.5 – 6.6	4.1 – 5.25
Gingival Height of base, mm	0 – 2.56	0.3 – 3.0	0.7
Gingival Height of superstructure, mm	0.5 – 6.0	0.5 – 6.0	0 – 5.83
Angulation, superstructure	up to 15°	up to 30°	up to 30°
Angulation, base	0°	0°	0°
Minimum wall thickness of superstructure, mm	0.4	0.4	0.43
Length of abutment post (length above the abutment collar/gingival height), mm	4.0	4.2 – 4.7	4.0
Connection	Engaging, Non-engaging	Engaging, Non-engaging	Not stated
Titanium Component (Base) Material	Titanium Alloy	Titanium Alloy, Co-Cr alloy	Titanium Alloy
Surface Treatment	Anodized, None	Anodized, None	Anodized
Superstructure	Zirconia, Cement	Zirconia, Cement	Zirconia, Cement
Used with implants	BL, TL	BL	BL
How Provided			
Sterility	Non-sterile	Non-sterile	Non-sterile
Usage	Single patient, single-use	Single patient, single-use	Single patient, single-use