JJGC Indústria e Comércio de Materiais Dentários S.A.
℅ Jennifer Jackson
Sr. Director, Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

August 18, 2025

Re: K250271
Trade/Device Name: Neodent Implant System - Zirconia Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA, PNP
Dated: July 15, 2025
Received: July 15, 2025

Dear Jennifer Jackson:

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

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

Submission Number *(if known)*

K250271

Device Name

Neodent Implant System - Zirconia Implant System

Indications for Use *(Describe)*

Zirconia Implants:
The Neodent Implant System is intended to be surgically placed in the bone of 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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusion loading. Multiple teeth applications can be rigidly splinted. The implants with length of 5 mm (short implants) may be used only with two-stage surgical procedures. The recommended healing time before loading is between 10 to 12 weeks.

Zi Transmucosal Cover Screw and Healing:
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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.

Zi Transmucosal Provisional Coping:
The Neodent Implant System is intended for surgical procedures in maxilla or mandible, providing 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 multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Zi Transmucosal Abutment Replacement Screw:
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.

Zi Transmucosal Universal Base:
The Universal Ceramic Base Zi Transmucosal 5.0 is an abutment placed over Neodent Zi Transmucosal 5.0 Ceramic Implant System in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base for Bridge:
The Zirconia Base for Bridge is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations. It may be used for cement or screw-retained multi-unit restorations. All digitally designed copings and/or crowns to be used with the

Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base C:
The Zirconia Base C is an abutment placed over Neodent Zirconia Implants in order to provide support for customized prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are screw- or cement-retained in esthetic areas over implants installed in the maxilla or mandible. All copings and/or crowns digitally designed for use with the Titanium Base C are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

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.

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810, USA Registration No.: 1222315 Owner/Operator No.: 9005052
	On the behalf of: JJGC Indústria e Comércio de Materiais Dentários S.A (dba Neodent) Av. Juscelino Kubitschek de Oliveira, 3291 Curitiba, Paraná, Brazil 81270-200 Registration No.: 3008261720 Owner/Operator No.: 10031702
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1 978 747-2509 Fax Number: +1 978 747-0023
Prepared By & Alternate Contact:	Leticia Milani Regulatory Affairs Analyst JJGC Indústria e Comércio de Materiais Dentários SA E-mail: leticia.milani@neodent.com
Date Prepared:	August 18, 2025

Name of the Device

Trade Names:	Neodent Implant System - Zirconia Implant System
Common Name:	Endosseous dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Device Classification:	II
Primary Product Code(s):	DZE

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

Secondary Product Code(s):	NHA, PNP
Classification Panel:	Dental Products

Predicate Device(s)

Primary Predicate:

K201491 Neodent Implant System – Zirconia Implant System

Reference Devices:

K210336 Neodent Implant System – Zirconia Implant System
K231803 Neodent Implant System – Zirconia Implant System
K101945 Neodent Implant System
K160964 Neodent Implant System – Titanium Bases for CEREC
K163194 Neodent Implant System – GM Line
K192229 Neodent Implant System – GM Titanium Base for Bridge
K123022 Neodent Implant System
K202942 Straumann® 4 mm Short Implants
K182620 MRI Compatibility for Existing Neodent Implant System

Device Description

This premarket notification includes new ceramic devices into Neodent Implant System, which are compatible with Zirconia Implant System. The Zirconia Implants and Abutments proposed on this submission are similar to devices already cleared in previous submissions of Neodent Implant System – Zirconia Implant System, according to predicate devices described above. This submission intends to expand the portfolio with new solutions and diameter, in order to provide more treatment options to the customers.

The Zirconia Implants are manufactured in Zirconia Y-TZP and are available in Bone Level (BL) or Tissue Level (TL or Transmucosal) configurations. The Zirconia Implants (BL) are available in a diameter of 5.0 mm and lengths in a range of 8 to 13 mm. The Zi Transmucosal Implants (TL) are available in a diameter of 5.0 mm and lengths in a range of 5 to 11.5 mm.

The Zi Transmucosal Healing and Cover Screw are temporary abutments manufactured in PEEK and used during the healing phase. They are compatible with the Zi Transmucosal Implants Ø5.0. The Zi Transmucosal Healing Abutment is available in the heights of 2 and 3.5mm.

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

The Zi Transmucosal Provisional Coping is a temporary abutment made of polycarbonate (PC) and has a double function: used for molding procedures or production of provisional restoration.

The Zi Transmucosal Abutment Replacement Screw is a prosthetic component manufactured in titanium alloy and used to fix the fix the Zi Transmucosal Base to the Zi Transmucosal Implant.

The Zi Transmucosal Universal Base is a two-piece abutment of base and top-half prosthetic structure to provide support for customized single-unit restorations over Zi Transmucosal Implant (TL). The base is manufactured in Zirconia Y-ZTP and used with a patient-specific top-half prosthetic structure. The two-piece abutment has a cementable portion of 4mm and is available with gingival heights of 0.3, 1.0 and 1.5 mm. The top-half prosthetic structure to be used with Zi Transmucosal Universal Base must be designed and milled in a Straumann Validated Milling center, using the following restoration materials and dimensions:

Material	Associated Material 510(k)	Minimum wall thickness	Maximum angulation
IPS e.max CAD HT	K132209	0.9 mm	30°
IPS e.max CAD LT	K132209	0.9 mm	
N!ce	K171773	1.0 mm	
IVOCLAR Multilink cement	K130436	N/A	
Zirconia N!ce® LT	K222836	0.4 mm	
Zirconia N!ce® HT	K222836	0.4 mm	
Zirconia N!ce® XT	K222836	0.4 mm	
PMMA N!ce	K071548	0.7 mm	
Panavia—Kuraray Cement	K150704	N/A	N/A

The Zi Base for Bridge is a two-piece abutment of base and top-half prosthetic structure to provide support for customized multi-unit restorations over Zirconia Implants (BL). The base is manufactured in Zirconia Y-ZTP and used with a patient-specific top-half prosthetic structure. The two-piece abutment has a cementable portion of 4mm and is available with gingival heights of 1.5, 2.5 and 3.5 mm. The top-half prosthetic structure to be used with Zi Base for Bridge must be designed and milled in a Straumann Validated Milling center, using the following restoration materials and dimensions:

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

Material	Associated Material 510(k)	Minimum wall thickness	Maximum angulation
Zirconia N!ce® LT	K222836	0.4 mm	30°
Zirconia N!ce® HT	K222836	0.4 mm	
Zirconia N!ce® XT	K222836	0.4 mm	
PMMA N!ce	K071548	0.7 mm	
Panavia—Kuraray Cement	K150704	N/A	N/A

The Zi Base C is a two-piece abutment of base and top-half prosthetic structure to provide support for customized single-unit restorations over Zirconia Implants (BL). The base is manufactured in Zirconia Y-ZTP and used with a patient-specific top-half prosthetic structure. The two-piece abutment has a cementable portion of 4mm and is available with gingival heights of 1.5, 2.5, 3.5 and 4.5 mm. The top-half prosthetic structure to be used with Zi Base C must be designed and milled in a Sirona InLab Validated Workflow, using the following restoration materials and dimensions:

Material	Associated Material 510(k)	Minimum wall thickness	Maximum angulation
IPS e.max CAD	K132209	0.9 mm	20°
IVOCLAR Multilink cement	K130436	N/A	N/A

All these abutments have an internal connection with the implants (ZiLock) and the prosthetic platform is identical for all subject devices described in this submission. They are intended for single use and provided sterile via Ethylene Oxide method, along with undergoing moist heat sterilization after end-user customization.

Intended Use

Zirconia Implants:

The Zirconia Implants are indicated for surgical intraoral installation in bone with density I / II or in bone III / IV, according to Lekholm & Zarb's bone classification (1985), in the maxilla or mandible. It may be used as a support for single-unit or multiple-unit prosthesis in immediate or conventional loading protocol. It may be installed immediately after the extraction of dental root. For the purposes of immediate loading, primary stability must reach, at least, 35 N.cm and the patient must present physiological occlusion.

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

Zi Transmucosal Cover Screw and Healing:

The Zirconia Cover Screw is intended for use during the osseointegration phase of Zirconia Implant 5.0, which will be rehabilitated using the delayed loading technique. It should remain submucosal, preventing tissue growth over the implant platform. The Zirconia Healing is used to maintain soft tissues during the osseointegration phase of Zirconia Implant 5.0, which will be rehabilitated using the delayed loading technique. It can be used during the implant installation surgery or during the reopening surgery (second surgical phase). It should be selected based on the available interocclusal space, the height of the transmucosal component, and the three-dimensional position of the implant. Both abutments are only available for Neodent Zirconia Implant System, being compatible with implants of the same line.

Zi Transmucosal Provisional Coping:

The Zi Transmucosal Provisional Coping has double function. It can be used for: molding procedure, identifying the three-dimensional position of the prosthetic abutment installed in the mouth; and, after customization, use as a Provisional Coping in the production of a provisional prosthesis cemented over the corresponding abutment from Neodent Zirconia Implant System. The abutment is only available for Zirconia Implant System, being compatible with implants of the same line.

Zi Transmucosal Abutment Replacement Screw:

The Zi Transmucosal Abutment Replacement Screw is indicated to fix the abutment to the implant.

Zi Transmucosal Universal Base:

The Zi Transmucosal Universal Base is indicated according to the interocclusal space available, existing gingival height and three-dimensional position of the implant. This product can be used in single-unit restorations. This product is compatible only with the Neodent Zirconia Implant System. All digitally designed restorations to be used with the Zi Transmucosal Universal Base devices are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base for Bridge:

The Zirconia Base for Bridge is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations. It may be used for cement or screw-retained multi-unit restorations. All digitally designed restorations to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base C:

The Zirconia Base C is indicated according to the interocclusal space available, existing gingival height and three-dimensional position of the implant. This product must be used in single-unit restorations. This product is compatible only with the Neodent Zirconia Implant System. This product must be used following the CAD/CAM technique through the Sirona Dental CAD/CAM System.

1.1 Indications for Use

Zirconia Implants:

The Neodent Implant System is intended to be surgically placed in the bone of 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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusion loading. Multiple teeth applications can be rigidly splinted. The implants with length of 5 mm (short implants) may be used only with two-stage surgical procedures. The recommended healing time before loading is between 10 to 12 weeks.

Zi Transmucosal Cover Screw and Healing:

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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.

Zi Transmucosal Provisional Coping:

The Neodent Implant System is intended for surgical procedures in maxilla or mandible, providing 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 multi-unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Zi Transmucosal Abutment Replacement Screw:

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.

Zi Transmucosal Universal Base:

The Universal Ceramic Base Zi Transmucosal 5.0 is an abutment placed over Neodent Zi Transmucosal 5.0 Ceramic Implant System in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base for Bridge:

The Zirconia Base for Bridge is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations. It may be used for cement or screw-retained multi-unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Zirconia Base C:

The Zirconia Base C is an abutment placed over Neodent Zirconia Implants in order to provide support for customized prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are screw- or cement-retained in esthetic areas over implants installed in the maxilla or mandible. All copings and/or crowns digitally designed for use with the Titanium Base C are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the following tables:

Table 42 – Table of Substantial Equivalence for Zirconia Implants

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE		
K Number	***K250271***	***K201491*** ***Neodent Implant System – Zirconia Implant System***	***K210336*** ***Neodent Implant System – Zirconia Implant System***	***K123022*** ***Neodent Implant System***	***K202942*** ***Straumann® 4 mm Short Implants***
Indications for Use	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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted. The implants with length of 5 mm (short implants) may be used only with two-stage surgical procedures. The recommended healing time before loading is between 10 to 12 weeks.	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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	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. Titamax WS implant is indicated for a delayed loading protocol. The Facility implant is indicated for replacement of maxillary lateral incisors, mandibular incisors or retention of overdentures.	Straumann® 4 mm Short Implants are indicated for fixed or removable reconstruction in situations of moderate to severely atrophic jawbone and with adequate bone quality that allows primary stability after implant insertion, where a longer implant cannot be placed due to limited vertical bone height. The recommended healing time before loading is between 10 to 12 weeks. The 4 mm Short Implants are specifically recommended for: • Fixed partial dentures/splinted units (one implant per unit) • Pontic cases in combination with at least one longer implant • Fully edentulous cases with at least one 4 mm Short Implant in combination with 2 longer implants in the anterior region and at least four total implants
Material	Yttrium-stabilized zirconium dioxide (Y-TZP).	Yttrium-stabilized zirconium dioxide (Y-TZP).	Yttrium-stabilized zirconium dioxide (Y-TZP).		
Implant-Abutment interface	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)		
Design	Cylindrical body geometry Apically tapered format Trapezoidal threads profile Bone and tissue level	Tapered body geometry Apically tapered format Trapezoidal threads profile Bone level	Tapered body geometry Apically tapered format Trapezoidal threads profile Bone level	Bone level	Tissue level
Diameter (Ø)	5.0 mm	4.3 mm	3.75 mm	4.0, 5.0 and 6.0 mm	4.1 and 4.8 mm

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE		
K Number	***K250271***	***K201491 Neodent Implant System – Zirconia Implant System***	***K210336 Neodent Implant System – Zirconia Implant System***	***K123022 Neodent Implant System***	***K202942 Straumann® 4 mm Short Implants***
Length	5; 8; 10; 11.5 and 13 mm	8; 10; 11.5 and 13 mm	10; 11.5 and 13 mm	5 and 6 mm	4.0 mm
Tissue level implant collar length	1.8 mm				1.8 mm
Single use	Yes	Yes	Yes	Yes	Yes
Sterilization Method	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.

Table 43 – Table of Substantial Equivalence for Zirconia Cover Screw and Healing Abutment

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	***K250271***	***K201491*** ***Neodent Implant System – Zirconia Implant System***	***K231803*** ***Neodent Implant System – Zirconia Implant System***
Indications for Use	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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	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 surgical procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with physiological occlusal loading. Multiple teeth applications can be rigidly splinted.	The PEEK CR Abutment is indicated to be used on Neodent Implants to provide support for prosthetic structures for up to 6 months. They can be used in single- or two-stage procedures and they are intended to be placed out of occlusion.
Material	PEEK Dental Grade	Cover Screw: Titanium alloy, according to ASTM F136. Healing: Yttrium-stabilized zirconium dioxide (Y-TZP)	PEEK Dental Grade
Implant-Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)
Overall dimensions	Diameter: 5.5 mm Gingival height: 2.0 and 3.5 mm	Diameter: 3.75 and 4.5 mm Gingival height: 1.5 and 2.5 mm	
Single Use	Yes	Yes	Yes
Sterilization Method	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.	Provided sterile via Ethylene Oxide to a SAL of $1x10^{-6}$.

Table 44 – Table of Substantial Equivalence for Zi Transmucosal Universal Base and Screw

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	***K250271***	***K201491*** ***Neodent Implant System – Zirconia Implant System***	***K231803*** ***Neodent Implant System – Zirconia Implant System***	***K223638*** ***Neodent Implant System – Helix Short Implant System***
Indications for Use	The Zi Universal Transmucosal Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center	The Helix Short Implant Titanium Base is a titanium base that is placed over Neodent dental implants to provide support for customized prosthetic restorations, such as copings and crowns. It is indicated for single- and multiple-structure restorations, screw- or cement-retained on implants installed in the maxilla or mandible. All digitally-designed copings and/or crowns to be used with the Neodent Titanium Base System must be sent to Straumann for manufacture at a validated milling center.
Material	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium Alloy ASTM F136.	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium Alloy ASTM F136.	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium Alloy ASTM F136.	
Implant-Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	
Diameter	Ø 5.5 mm	Ø 3.75 and 4.5 mm	Ø 3.75 and 4.5 mm	
Gingival Height	0.3, 1.0 and 3.5 mm	1.5 and 2.5 mm	3.5 and 4.5 mm	0.2; 1.5, 2.5 and 3.5 mm
Maximum Angulation of Prosthetic Structure	30°	30°	30°	
Design Workflow	Zi Universal Base library on Dental Wings, Exocad and 3Shape softwares.	Zirconia Base library on Dental Wings, Exocad and 3Shape softwares.	Zirconia Base library on Dental Wings, Exocad and 3Shape softwares.	

Traditional 510(k) Submission

Neodent Implant System - Zirconia Implant System

510(k) Summary

<table>
<tr><th>FEATURE</th><th>PROPOSED DEVICE</th><th>PRIMARY PREDICATE DEVICE</th><th colspan="2">REFERENCE PREDICATE DEVICE</th></tr>
<tr><td>K Number</td><td>K250271</td><td>K201491
Neodent Implant System – Zirconia Implant System</td><td>K231803
Neodent Implant System – Zirconia Implant System</td><td>K223638
Neodent Implant System – Helix Short Implant System</td></tr>
<tr><td>Manufacturing Workflow</td><td>Straumann Milling Center</td><td>Straumann Milling Center</td><td>Straumann Milling Center</td><td></td></tr>
<tr><td>Top Half Material</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th></tr>
<tr><td>IPS e.max CAD HT</td><td>0.9 mm</td></tr>
<tr><td>IPS e.max CAD LT</td><td>0.9 mm</td></tr>
<tr><td>Zirconia N!ce® LT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce® HT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce® XT</td><td>0.4 mm</td></tr>
<tr><td>PMMA N!ce</td><td>0.7 mm</td></tr>
<tr><td>N!ce</td><td>1.0 mm</td></tr>
</table>
*PMMA N!ce is indicated to remain in the mouth only for up to 180 days
</td><td>
<table>
<tr><th>Material</th><th>Minimum Thickness</th></tr>
<tr><td>IPS e.max CAD LT</td><td>0.9 mm</td></tr>
<tr><td>IPS e.max CAD Press</td><td>0.9 mm</td></tr>
<tr><td>Zirconia N!ce LT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce HT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce XT</td><td>0.4 mm</td></tr>
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<tr><td>IPS e.max CAD Press</td><td>0.9 mm</td></tr>
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<tr><td>Zirconia N!ce XT</td><td>0.4 mm</td></tr>
<tr><td>PMMA N!ce</td><td>0.7 mm</td></tr>
<tr><td>N!ce</td><td>1.0 mm</td></tr>
</table>
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</td><td></td></tr>
<tr><td>Minimum Abutment Post-height</td><td>4 mm</td><td>4 mm</td><td>4 mm</td><td>4.0 – 6.0mm</td></tr>
<tr><td>Single Use</td><td>Yes</td><td>Yes</td><td>Yes</td><td></td></tr>
<tr><td>Sterilization Method</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td></td></tr>
</table>

Table 45 – Table of Substantial Equivalence for Zirconia Base for Bridge

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE
K Number	***K250271***	***K201491*** ***Neodent Implant System – Zirconia Implant System***	***K192229*** *Neodent Implant System – GM Titanium Base for Bridge*
Indications for Use	The Zirconia Base for Bridge is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations. It may be used for cement or screw-retained multi-unit restorations. All digitally designed restorations to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for patient-specific prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	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 to be used with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center. The GM Titanium Base for Bridge is indicated for cement or screw-retained multi-unit restorations.
Material	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium Alloy ASTM F136.	
Implant-Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	
Diameter	Ø 4.5 mm	Ø 3.75 and 4.5 mm	
Gingival Height	1.5, 2.5 and 3.5 mm	1.5 and 2.5 mm	
Maximum Angulation of Prosthetic Structure	30°	30°	
Design Workflow	Zi Universal Base library on Dental Wings, Exocad and 3Shape softwares.	Zirconia Base library on Dental Wings, Exocad and 3Shape softwares.	
Manufacturing Workflow	Straumann Milling Center	Straumann Milling Center	

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Neodent Implant System - Zirconia Implant System

510(k) Summary

<table>
<tr><th>FEATURE</th><th>PROPOSED DEVICE</th><th>PRIMARY PREDICATE DEVICE</th><th>REFERENCE PREDICATE DEVICE</th></tr>
<tr><td>K Number</td><td>K250271</td><td>K201491
Neodent Implant System – Zirconia Implant System</td><td>K192229
Neodent Implant System – GM Titanium Base for Bridge</td></tr>
<tr><td>Top Half Material</td><td>
<table>
<tr><th>Material</th><th>Minimum thickness</th></tr>
<tr><td>Zirconia N!ce® LT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce® HT</td><td>0.4 mm</td></tr>
<tr><td>Zirconia N!ce® XT</td><td>0.4 mm</td></tr>
<tr><td>PMMA N!ce</td><td>0.7 mm</td></tr>
</table>
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<tr><th>Material</th><th>Minimum Thickness</th></tr>
<tr><td>IPS e.max CAD LT</td><td>0.9 mm</td></tr>
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</td><td></td></tr>
<tr><td>Single Use</td><td>Yes</td><td>Yes</td><td></td></tr>
<tr><td>Sterilization Method</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td></td></tr>
</table>

Table 46 – Table of Substantial Equivalence Zirconia Base C

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	REFERENCE PREDICATE DEVICE	
K Number	***K250271***	***K201491*** ***Neodent Implant System – Zirconia Implant System***	***K231803*** ***Neodent Implant System – Zirconia Implant System***	***K160964*** ***Neodent Implant System – Titanium Bases for CEREC***
Indications for Use	The Zirconia Base C is an abutment placed over Neodent Zirconia Implants in order to provide support for customized prosthetic restorations, such as copings or crowns. It may be used for single-unit restorations that are screw- or cement-retained in esthetic areas over implants installed in the maxilla or mandible. All copings and/or crowns digitally designed for use with the Titanium Base C are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw-retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.	The Zirconia Base is an abutment placed over Neodent Zirconia Implants in order to provide support for custom-made prosthetic restorations, such as copings or crowns. It may be used for cement- or screw retained single unit restorations. All digitally designed copings and/or crowns to be used with the Neodent Zirconia Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center	The Titanium Base for CEREC is a titanium component that is placed over Neodent Implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base for CEREC are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.
Material	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	Base: Yttrium-stabilized zirconium dioxide (Y-TZP). Screw: Titanium alloy ASTM F136.	
Implant-Abutment Connection	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	Straight internal connection indexing features (Zilock)	
Gingival height	1.5, 2.5, 3.5 and 4.5 mm	1.5 and 2.5 mm	3.5 and 4.5 mm	0.8, 1.5, 2.5, 3.5, 4.5, 5.5 and 6.5 mm
Maximum Angulation of Prosthetic Structure	20°	30°	**30°**	**20°**
Design Workflow	Zirconia Base C library on Sirona CEREC Software.	Zirconia Base library on Dental Wings, Exocad and 3Shape softwares.	Zirconia Base library on Dental Wings, Exocad and 3Shape softwares.	Titanium Base C library on Sirona CEREC Software.
Manufacturing Workflow	Sirona InLab Milling Unit	Straumann Milling Center	Straumann Milling Center	Sirona InLab Milling Unit

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Neodent Implant System - Zirconia Implant System

510(k) Summary

<table>
<tr><th>FEATURE</th><th>PROPOSED DEVICE</th><th>PRIMARY PREDICATE DEVICE</th><th colspan="2">REFERENCE PREDICATE DEVICE</th></tr>
<tr><td>K Number</td><td>K250271</td><td>K201491
Neodent Implant System – Zirconia Implant System</td><td>K231803
Neodent Implant System – Zirconia Implant System</td><td>K160964
Neodent Implant System – Titanium Bases for CEREC</td></tr>
<tr><td>Top Half Material</td><td><table><tr><th>Material</th><th>Minimum Thickness</th></tr><tr><td>IPS e.max CAD</td><td>0.9 mm</td></tr></table></td><td><table><tr><th>Material</th><th>Minimum Thickness</th></tr><tr><td>IPS e.max CAD LT</td><td>0.9 mm</td></tr><tr><td>IPS e.max CAD Press</td><td>0.9 mm</td></tr><tr><td>Zirconia N!ce LT</td><td>0.4 mm</td></tr><tr><td>Zirconia N!ce HT</td><td>0.4 mm</td></tr><tr><td>Zirconia N!ce XT</td><td>0.4 mm</td></tr><tr><td>PMMA N!ce</td><td>0.7 mm</td></tr><tr><td>N!ce</td><td>1.0 mm</td></tr></table>*PMMA N!ce is used for provisional prosthetic restorations.
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<tr><td>Minimum Abutment Post-height</td><td>4.7 mm</td><td>4 mm</td><td>4 mm</td><td>4.7 mm</td></tr>
<tr><td>Single Use</td><td>Yes</td><td>Yes</td><td>Yes</td><td></td></tr>
<tr><td>Sterilization Method</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td>Provided sterile via Ethylene Oxide and end-user Moist Heat sterilized to a SAL of $1x10^{-6}$</td><td></td></tr>
</table>

Performance Testing

Bench Testing

Assessments regarding dynamic fatigue testing were conducted according to the FDA guidance document “Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” and ISO 14801 “Dentistry — Implants — Dynamic loading test for endosseous dental implants”. For dynamic fatigue tests, the results demonstrated that in identical conditions, the subject devices exhibit a level of performance substantial equivalent to the predicate and reference devices.

Torsion tests were also performed to evaluate the strength of the screw used to fix all subject abutments against maximum twisting forces. The results prove that there is an adequate torsion strength in accordance with the installation torque recommended in IFU. Insertion tests were performed to evaluate the insertion torque of the Zirconia Implant System when inserted into sawbones material representing bone type I, II, III and IV.

The Implant Surface Area simulation and Pull Out Test were also made to evaluate and represent the clinical use of the Zi Transmucosal Implant less than 7mm of length. In regular condition, although the results demonstrate that the subject devices have a greater surface area when compared to the reference devices. Pull Out Test results support the surface evaluation with higher resistance values for the subject devices.

Referenced K210336 and K201491 for the surface analyses for wear or other damage, including microscopic and SEM images, of the internal thread area of the ceramic implant body and mated ceramic two-piece abutment via titanium abutment fixation screw, following cyclic fatigue loading per recommended ISO 14801. Referenced K201491 for surface treatment and cleaning procedure and XPS (X-ray photoelectron spectroscopy). All subject devices are manufactured from the same Zirconia raw material, equipment, processes and parameters and receive the same surface treatment as the reference devices.

Software Validation

A study to demonstrate the software validation of Sirona Digital Workflow applicable to Zirconia Bases C were performed. The analysis was based on the compatibility with the blocks available in Sirona Software, as well as in the verification that critical design parameters - such as minimum wall thickness and maximum angulation - are respected and properly monitored by the system.

The results show that the accuracy requirement was met using the Sirona Digital Workflow.

MRI Compatibility Testing

An assessment was made to demonstrate that the MR conditional labeling from K182620 is applicable to the subject devices, and a patient treated with them can be safely scanned observing the parameters previously established per reference devices.

Biocompatibility Testing

Biological assessments were performed according to ISO 10993-1 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*" and to the FDA Guidance document "*Use of International Standard ISO 10993- 1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process', Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016*" for each subject device.

Representative samples of the subject devices were subjected to the following:

• Biological Safety Assessment guided by ISO 10993-1.

• Chemical characterization was performed per ISO 10993-18.

• Cytotoxicity testing was performed per ISO 10993-5.

The subject devices are equivalent in material and manufacturing processes to the primary predicate and reference devices, therefore, no new issues regarding biocompatibility were raised and no additional biocompatibility testing was required.

Sterilization validation

For the proposed devices supplied sterile via Ethylene Oxide (EO), the method was validated to a sterility assurance level (SAL) of $1x10^{-6}$ in accordance with ISO 11135:2014, "*Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*". EO sterilization residuals have been verified to be less than the maximum allowable limits as defined in ISO 10993-7 "*Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals*".

For proposed devices that must be sterilized before installation in the mouth, the steam sterilization methos was validated 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*", using the parameters described in IFU.

The sterilization of the subject device are identical to the sterilization already cleared for the primary and reference predicate devices.

The Subject devices are not represented to be "pyrogen free".

The endotoxin test and validation are performed in JJGC, in microbiology laboratory, in accordance with the standard ANSI/AAMI ST72:2011 – Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing, ISO 11737-3 - Sterilization of health care products — Microbiological methods - Bacterial endotoxin testing and with US Pharmacopeia chapter 85 – Bacterial Endotoxins Test. The test method aims at the determination of bacterial endotoxins in implant devices supplied sterile using the turbidimetric kinetic method. The obtained results were <0,05 EU/device.

Shelf Life

The expiration date of the devices was determined considering the integrity of the product and the packaging tests after shelf-life testing. The packaging of the proposed devices is identical to the packaging of the primary predicate and reference devices. The Shelf Life for Zirconia Devices is 5 years.

Clinical Literature

Clinical literature review was conducted to support the safety of Zi Transmucosal Implant less than 7mm of length. The animal studies demonstrated that Titanium and Zirconia implants yielded very similar BIC% results after a comparable healing period. Consequently, both implants are

expected to achieve similar osseointegration outcomes and can be compared to demonstrate clinical behavior. Additionally, histomorphometry evaluation and secondary parameters, such as the first bone-to-implant contact (fBIC) and the bone area to total area (BATA) ratio, also reinforced the ability of zirconia implants to promote bone formation around them in a manner equivalent to titanium implants. Thus, Zirconia Implants lower than 7mm of length represent a reliable alternative for rehabilitating edentulous patients, when used according to the IFU orientations.

Conclusion

The subject devices and the primary predicate device have similar indications for use, intended use, design, raw material and overall dimensions. Thus, all documentation submitted in this premarket notification demonstrate that the proposed devices are substantially equivalent to the primary predicate and reference devices.