May 14, 2025

CeraRoot SL
Josep Oliva-Ochoa
Dentist- Implantologist / President
Parpers 13
Les Franqueses del Valles, Barcelona 08520
SPAIN

Re: K242072
Trade/Device Name: CeraRoot TL Implant System (TL)
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 18, 2025
Received: April 17, 2025

Dear Josep Oliva-Ochoa:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242072

Device Name

CeraRoot TL Implant System (TL)

Indications for Use *(Describe)*

CeraRoot TL dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot TL dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot TL implants can be placed in immediate or delayed tooth extractions. CeraRoot TL implants are intended for delayed loading. The CeraRoot TL dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.

The CeraRoot TL implants are the two-piece tissue level variant of the original CeraRoot implant system (one-piece).

CeraRoot TL abutments are industrially manufactured prosthetic components made out from the same material as the implant.

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.

510(k) number: K242072

1.Submitters contact information:

CeraRoot S.L.
Address: Parpers, 13. 08520 Les Franqueses del Vallès .(Barcelona) SPAIN
Phone: (+34)768 3962 (+1)800 485 1613
Contact persons: Josep Oliva-Ochoa, Xavier Oliva-Ochoa
Email: josep.oliva@ceraroot.com xavi.oliva@ceraroot.com
Date written: May 13, 2025.

2.Device name and classification

Trade Name: CeraRoot TL Implant System
Common Name: Endosseous Dental Implant
Classification Name: Endosseous Dental Implant
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 21 CFR 872.3640
Classification: Class II

3.Predicate Devices

3.1.Primary predicate device CeraRoot TL Implant System

Device	Device Owner/ Trade Name	510(k) #	Product Code
Primary Predicate	CeraRoot SL / CeraRoot Implant System	K093595	DZE (Implant, Endosseous, Root-Form)

3.2.Reference devices CeraRoot TL Implant System

Device	Device Owner/ Trade Name	510(k) #	Product Code
Reference	Swiss Dental Solutions SDS2.2 dental implant	K190406	DZE (Implant, Endosseous, Root-Form)
Reference	Z-Systems AG Z5c Dental Implant	K132881	DZE (Implant, Endosseous, Root-Form)
Reference	Dental Point AG Zeramex® P6 Dental Implant System	K163043	DZE (Implant, Endosseous, Root-Form)
Reference	Straumann USA LLC Straumann PURE CeramicImplant System	K180477	DZE (Implant, Endosseous, Root-Form)

3.3.Reference devices CeraRoot TL abutments

Device	Device Owner/ Trade Name	510(k) #	Product Code
Reference	Swiss Dental Solutions SDS2.2 dental implant	K190406	NHA (Endosseous Dental Implant Abutment)
Reference	Z-Systems AG Z5c Dental Implant	K132881	NHA (Endosseous Dental Implant Abutment)
Reference	Dental Point AG Zeramex® P6 Dental Implant System	K163043	NHA (Endosseous Dental Implant Abutment)
Reference	Straumann USA LLC Straumann PURE CeramicImplant System	K180477	NHA (Endosseous Dental Implant Abutment)

3.4. Other Reference devices

Device	Device Owner/ Trade Name	510(k) #	Product Code
Reference	IVOCLAR VIVADENT INC. SPEEDCEM	K091019	EMA (Cement, Dental)
Reference	VOCO GmbH Clip Flow	K153493	EBF (Material, Tooth Shade, Resin)

4.Device Description

4.1.CeraRoot TL dental implant

The CeraRoot TL Implant System is the two-piece tissue level variant of the original ceramic dental implant one-piece CeraRoot Implant System (K093595) available since 2011 in the USA and 2006 in Europe. CeraRoot® dental implants are made of Y-TZP zirconium dioxide ceramics in accordance with ISO 13356.
CeraRoot® dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The outer surface is acid etched for good osseointegration. The new TL (two-piece) variants are available in different lengths (8,10, 12 and 14mm) and only for the models CeraRoot 34TL (∅ 5mm), CeraRoot 21TL (∅ 5.6mm) and CeraRoot 16TL (∅ 7mm).
The implants are provided sterile in sterile packaging and are intended for single use. CeraRoot implants must not be re-sterilized or disinfected either.

4.2.CeraRoot TL abutments

The CeraRoot TL abutments are made of the same Y-TZP ceramic material as the implants, and are attached to the CeraRoot TL implants by cementation. After the cementation of the abutments into the implant then the restorative prosthesis can be custom-made, produced and cemented on top to finish the treatment.
The CeraRoot TL abutments are available with the lengths 4.3 and 5.8 mm.
The CeraRoot TL abutments are provided non-sterile. They are intended for single use and must not be reused. Before use they must be cleaned, disinfected and sterilized according to the instructions given in the “instructions for use of CeraRoot TL abutments” document.

5.Indications for use

	Primary Predicate Device	Proposed Device
510k no.	**K093595**	**Subject K242072**
Trade Name	**CeraRoot Implant System**	**CeraRoot TL Implant System**
Product Code	DZE (Implant, Endosseous, Root-Form)	DZE (Implant, Endosseous, Root-Form)
Secondary Code	/	NHA (Endosseous Dental Implant Abutment)
Indications for use	CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.	CeraRoot TL dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot TL dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot TL implants can be placed in immediate or delayed tooth extractions. CeraRoot TL implants are intended for delayed loading. The CeraRoot TL dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies. The CeraRoot TL implants are the two-piece tissue level variant of the original CeraRoot implant system (one-piece). CeraRoot TL abutments are industrially manufactured prosthetic components made out from the same material as the implant.

The Indications for Use of the subject device are the same as of the primary predicate device with only some minor differences as described hereafter. The prosthetic components (abutments) are different due to the two-piece design of the subject device compared to the one-piece design of the primary predicate device. The use of these components with the subject device are consistent with the use of similar components of the primary predicate device and therefore do not raise new questions about the safety and effectiveness when compared to the predicate device.

5.1.Comparison of the modified proposed/subject device to the primary cleared device in tabular format

	Primary Predicate Device	Proposed Device
510k no.	**K093595**	**Subject K242072**
Trade Name	**CeraRoot Implant System**	**CeraRoot TL Implant System**
Product Code	DZE (Implant, Endosseous, Root-Form)	DZE (Implant, Endosseous, Root-Form)
Secondary Code	/	NHA (Endosseous Dental Implant Abutment)
Indications for use	CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are	CeraRoot TL dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot TL dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot TL implants can be placed in immediate or delayed tooth extractions. CeraRoot TL implants are intended for delayed loading. The CeraRoot TL dental implants are specially indicated in

	Primary Predicate Device	Proposed Device
510k no.	**K093595**	**Subject K242072**
Trade Name	**CeraRoot Implant System**	**CeraRoot TL Implant System**
	specially indicated in patients with metal allergies and chronic illness due to metal allergies.	patients with metal allergies and chronic illness due to metal allergies. The CeraRoot TL implants are the two-piece tissue level variant of the original CeraRoot implant system (one-piece). CeraRoot TL abutments are industrially manufactured prosthetic components made out from the same material as the implant.
Material	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356
Production Process	Milling and Sintering	Milling and Sintering
Surface finish	Acid Etching	Acid Etching
Sterilization	Ethylene oxide	Ethylene oxide
Packaging	Primary: vial and SBS Secondary: Carton Box	Primary: vial and SBS Secondary: Carton Box
Restoration	one-piece implant system	Two-piece implant system
Abutment	Build-in with the implant	Separate device, to be cemented on the implant after its osseointegration
Model CeraRoot 12	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.1 ∅ (mm) prosthetic: 4.1 Abutment height: 5	No TL variant
Model CeraRoot 14	L(mm): 10,12,14 ∅ (mm) intrabone: 3.5-4.8 ∅ (mm) prosthetic: 5-7 Abutment height: 4	No TL variant
Model CeraRoot 34	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.1-4.8 ∅ (mm) prosthetic: 5 Abutment height: 4.3	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.1-4.8 ∅ (mm) prosthetic: 5 Abutment height: 4.3, 5.8
Model CeraRoot 34L	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.1-4.8 ∅ (mm) prosthetic: 5 Abutment height: 5.8	No TL variant
Model CeraRoot 21	L(mm): 10,12,14 ∅ (mm) intrabone: 4.1-4.8 ∅ (mm) prosthetic: 6 Abutment height: 6.2	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.1-4.8 ∅ (mm) prosthetic: 5.6 Abutment height: 4.3, 5.8
Model CeraRoot 11	L(mm): 10,12,14 ∅ (mm) intrabone: 4.8-6 ∅ (mm) prosthetic: 6.5 Abutment height: 7	No TL variant
Model CeraRoot 16	L(mm): 10,12,14 ∅ (mm) intrabone: 4.8-6.5 ∅ (mm) prosthetic: 8 Abutment height: 4	L(mm): 8,10,12,14 ∅ (mm) intrabone: 4.8-6.5 ∅ (mm) prosthetic: 7 Abutment height: 4.3, 5.8

New product references (REF):

	DZE (Implant, Endosseous, Root-Form)	NHA (Endosseous Dental Implant Abutment)
Implant Models	**REF:**	**REF:**
34TL	342.008 - (8mm)	342.104 - (4.3mm)

	DZE (Implant, Endosseous, Root-Form)	NHA (Endosseous Dental Implant Abutment)
	342.010 - (10mm) 342.012 - (12mm) 342.014 (14mm)	342.106 - (5.8mm)
21TL	212.008 - (8mm) 212.010 - (10mm) 212.012 - (12mm) 212.014 (14mm)	342.104 - (4.3mm) 342.106 - (5.8mm)
16TL	162.008 - (8mm) 162.010 - (10mm) 162.012 - (12mm) 162.014 - (14mm)	162.104 - (4.3mm) 162.106 - (5.8mm)
Material	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356

Bellow reference devices were also used in this premarket notification to capture technological characteristics found in the subject device that were not present in the primary predicate device (due to its one-piece design). These minor differences in technical characteristics as identified in the table below do not raise any new questions of safety and effectiveness between the subject and primary predicate device, as these differences are present in the reference devices, which have undergone FDA review and are legally marketed

6.Comparison of Technological characteristics of substantial equivalence devices

FEATURE	PROPOSED	PRIMARY PREDICATE	REFERENCE DEVICES			
	Subject K242072 CeraRoot TL Implant System	**K093595 CeraRoot Implant System**	**K190406 SDS2.2 dental implant**	**K132881 Z5c**	**K163043 Zeramex® P6**	**K180477 PURE Ceramic Implant System**
Indications for use	CeraRoot TL dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot TL dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot TL implants can be placed in immediate or delayed tooth extractions. CeraRoot TL implants are intended for delayed loading. The CeraRoot TL dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies. The CeraRoot TL implants are the two-piece tissue level variant of the original CeraRoot implant system (one-piece). CeraRoot TL abutments are industrially manufactured prosthetic components made out from the same material as the implant.	CeraRoot dental implants are especially designed for the surgical implantation in the maxilla and mandible for the retention of fixed prosthetic devices, such as an artificial tooth, in order to restore patient aesthetics and chewing function. The CeraRoot dental implants can be used for single or multiple unit restorations in splinted or non-splinted applications. CeraRoot implants can be placed in immediate or delayed tooth extractions. CeraRoot implants are not intended for immediate loading. The CeraRoot dental implants are specially indicated in patients with metal allergies and chronic illness due to metal allergies.	SDS2.2 dental implants are intended as artificial replacements to be placed in the human upper or lower jaw to provide anchor points for the prosthetic restoration. They are indicated for transgingival healing. The implants are indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. SDS2.2 standard implant posts and SDS2.2 standard screws are industrially manufactured prosthetic components. They are connected to the SDS2.2 dental implant and enable the fixation of prosthetic restorations.	Z5c implants are designed for surgical implantation into the upper and lower jaw for the attachment of prosthodontic appliances to replace missing teeth. Z5c implant system is also suitable for patients with metal allergies and the chronic diseases resulting from them. Z5c implants are intended for delayed loading.	The Zeramex® P6 Dental Implant System is intended to be surgically placed in the bone of the upper and lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore aesthetics and chewing function. The Zeramex® P6 Dental Implant System can be used for single or multiple unit restorations. The Zeramex® P6 implants are intended for delayed loading. The Zeramex® P6 implants are specially indicated for patients with metal allergies/ intolerances and chronic illness due to metal allergies/intolerances. The Zeramex® P6 (Ø3.3mm SN) implant may only be used in the anterior teeth in the lower jaw and lateral incisor in the upper jaw.	The Straumann PURE Ceramic Implant is indicated for the restoration of single-tooth gaps and in edentulous or partially edentulous jaws. The prosthetic restorations used are single crowns, fixed partial or full dentures, which are connected to the implants through the corresponding components. The CI RD Straumann PUREbase Abutment is a titanium base placed onto Straumann ceramic dental implants to provide support for customized prosthetic restorations and is indicated for screw-retained single tooth or cement-retained single tooth and bridge restorations. All digitally designed copings and/or crowns for use with the Straumann® Variobase Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.
Design	Two-Piece	one-piece	Two-Piece	Two-Piece	Two-Piece	Two-Piece
Implant abutment connection	Cemented	NA	Cemented	Screw-Cement	Screw	Screw
Cement used	SPEEDCEM (K091019)	NA	Ketac Cem (K002793)	Panavia (K032455)	Panavia (K032455)	NA
Restoration Mode of attachment	Cemented	Cemented	Cemented	Cemented	Cemented	Cemented
Material	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356	Y-TZP according to ISO 13356	Aluminum toughened zirconia	Aluminum toughened zirconia	Y-TZP according to ISO 13356

6.Comparison of Technological characteristics of substantial equivalence devices

FEATURE	PROPOSED	PRIMARY PREDICATE	REFERENCE DEVICES			
	Subject K242072 CeraRoot TL Implant System	**K093595 CeraRoot Implant System**	**K190406 SDS2.2 dental implant**	**K132881 Z5c**	**K163043 Zeramex® P6**	**K180477 PURE Ceramic Implant System**
Manu facturing Technology	Turning	Turning	Turning	Turning	Turning	CIM
Implant endosteal Length	8, 10, 12 and14 mm	8, 10, 12 and 14 mm	8, 11 and 14 mm	10, 11.5, 13 and 14 mm	8, 10 and 12 mm	8, 10, 12 and 14 mm
Implant Coronal diameter	Ø5, 5.6 and 7 mm	Ø4.1, 5, 6.5, 7 and 8 mm	Ø5 and 6 mm	Ø4.8 and 6mm	Ø4 and 4.8 mm	Ø3.5 and 4.8 mm
Implant endosteal diameter	Ø4.8 and 6.5 mm	Ø4.1, 4.8, and 6.5 mm	Ø	Ø4 and 5mm	Ø3.3, 4.1 and 4.8 mm	Ø3.3 and 4.1 mm
Abutment material	Y-TZP according to ISO 13356	NA	Y-TZP according to ISO 13356	Aluminum toughened zirconia	Aluminum toughened zirconia	Ti-6Al-7Nb
Abutment height	4.3 and 5.8 mm	NA	2mm	4.5 and 5.5 mm	5.5, 6.5 and 7mm	6.5 and 8 mm
Abutment angulation	0º (straight)	NA	0º (straight) 15º (angled)	0º (straight) 15º (angled)	0º (straight)	0º (straight)
Sterilization method	Ethylene Oxide	Ethylene Oxide	Radiation	Plasma	Steam	Ethylene Oxide
Surface finish	Acid Etched	Acid Etched	Sand Blasted	Grit blasted and laser modified	Sandblasted and etched	Sand blasted acid etched

7.Substantial equivalence discussion

7.1.Substantial equivalence discussion CeraRoot TL implant system

As demonstrated in the substantial equivalence discussion the CeraRoot TL implant subject device is equivalent to the selected predicate devices.
The subject device is equivalent to the primary predicate device in terms of intended use, technological characteristics, material and design key elements (including diameter and length, production technology, implant surface topography, sterile packaging, shoulder design, etc.).
Certain differences from the primary predicate device are covered by the reference devices as follows:

- In terms of anti-rotation protection, the subject device is designed with an internal heart shape, while the primary predicate device features a one-piece design. This difference is covered by the reference devices K190406 and K163043, which are also providing an internal hexagon for anti-rotation protection.
- Regarding available abutments, the primary predicate device features a one-piece design that requires no additional abutments. This difference is covered by the reference devices K132881, K190406 and K163043, which are containing abutments in similar designs.
- In regard to protecting the implant connection without a cover screw during the healing phase, the subject device uses temporary filling material and PTFE to seal the connection. This difference was tested with end-users and demonstrated removal of the material intact with no damage to the internal connection.

Based on this comparison it can be concluded that the subject device is substantially equivalent to the predicate devices listed.

7.2.Substantial equivalence discussion CeraRoot TL abutments

As demonstrated in the substantial equivalence discussion the CeraRoot TL subject device is equivalent to the selected predicate devices.
CeraRoot TL abutments are substantially equivalent in terms of material, intended use, indications for use and geometry to the reference devices listed above.
Certain differences from the reference devices are covered by following facts:

- Regarding the cements used for bonding, CeraRoot TL implant posts are required to be bonded using the dental cement SpeedCem™, Ketac™Cem Automix, whereas the reference devices recommend Ketac™Cem Automix and Panavia™ SA Cement Automix. The difference is bridged by the fact that all stated dental cements are cleared medical devices, cleared under K091019, K032455 and K002793.
- Additionally, the dental cement SpeedCem™ (K091019) has been tested successfully in the context of fatigue testing according to ISO 14801.
- The subject device utilizes cementation of the restoration onto the implant gingival collar, which is similar to that in K190406 but does not include reduction of the gingival collar. Instead, the device requires the creation of a feather margin to promote a proper emergence profile and retaining a minimum of 5mm of stump height combining the implant and abutment. This is necessary to ensure prosthesis retention and reduce the risk of debonding.

Based on this comparison it can be concluded that the subject device is substantially equivalent to the predicate devices listed.

8.Non clinical testing

8.1.Biocompatibility

Concerning biocompatibility, the components of the CeraRoot TL implant system described in the biocompatibility document were subjected to a biological evaluation according to ISO 10993-1 including cytotoxicity tests according to ISO 10993-5.
For the manufacturing of CeraRoot TL implant system, identical materials are used in the primary predicate devices with the same type and duration of patient contact (see also substantial equivalence comparison).
Concerning the residues from manufacturing processes, the biocompatibility is demonstrated by the tests regarding Cytotoxicity, Bioburden and Endotoxins by an accredited laboratory.
The methods applied for manufacturing, cleaning and sterilization are established validated procedures for several years and are identical to the methods applied for the primary predicate device, cleared under K093595.
Biological evaluation for ethylene oxide sterilization residuals according to ISO 10993-7 was conducted in the primary predicate, K093595."

8.2.Performance testing

Performance testing of CeraRoot TL implant system was planned regarding the risk analysis according to ISO 14971.
The indicated performance tests were derived and have been projected.
As a result of the risk analysis and regarding the applicable FDA guidance the laboratory testing "fatigue testing according to ISO14801" was identified as essential. The testing results were analyzed and evaluated. They demonstrate that the CeraRoot TL implant system meets the existing requirements and acceptance criteria like the predicate devices.
Other tests like biocompatibility, sterility, packaging integrity were discarded based on the risk analysis because it was already covered by the primary predicate device which was identical in raw material and the whole manufacturing process. No additional risks were identified for the new subject device CeraRoot TL two-piece variant. The validation results of the original primary predicate have demonstrated that the cleaning, disinfection and sterilization process meet the defined results.
For the acid etched surface finish, the primary predicate, K093595, included testing for SEM surface analysis and surface topography."

9.Sterilization validation and shelf life.

The sterilization and shelf life validations have been performed with the primary predicate CeraRoot implant system (K093595 the original one-piece variant). The one-piece (predicate device) and two-piece implants (subject device) are two implant variants that share the same and exact processes for manufacturing, cleaning, sterilization and packaging. Furthermore, a risk analysis (ISO 14971) did not introduce any new risks that may require the realization of a new revalidation.

The sterilization validation was conducted in compliance with ISO 11135. The validation results have proved a sterility assurance level of ≤ 10^{-6}. For the packaging system a performance validation acc. to ISO 11607-1 and ISO 11607-2 was completed. The validation results have demonstrated that the packaging system for CeraRoot implants fulfilled the requirements regarding the packaging performance during sterilization and storage till 5 years accelerated aging.

For the products provided non-sterile, the validation of end-user sterilization has been performed according to ISO 17665. The validation results have demonstrated that the stated cleaning, disinfection and sterilization process meet the defined results.

10.Animal testing

Not applicable, bench testing is performed

11.Clinical testing

Not applicable, CeraRoot TL implant system does not meet one of the characteristics defined by FDA for which clinical studies are needed

12.Summary

Based on the results of Substantial Equivalence Discussion, Performance testing results and the compliance with applicable standards, the CeraRoot TL implant system and abutments are considered substantially equivalent to the named predicate devices.

Existing minor differences in design and technology between the subject device and the predicate devices do not raise any new questions of safety and effectiveness. Therefore, it can be concluded that the CeraRoot TL implant system is substantially equivalent to the predicate devices.

13.Applicable standards

CeraRoot TL implant system meets a number applicable standards including the ones listed in the following table:

Standard	No.	Title	Edition
Safety / Functional			
EN	1642	Dentistry. Medical devices for dentistry. Dental Implants	2011
ISO	13356	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	2015
EN ISO	14801	Dentistry -- Implants -- Dynamic fatigue test for endosseous dental implants (= ISO 14801:2016)	2016
ISO	6872	Dentistry - Ceramic materials.	2015 / Amd. 1:2018
Biocompatibility			
ISO	10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2018
ISO	10993-5	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity	2009

Standard	No.	Title	Edition
ISO	10993-7	Biological evaluation of medical devices-Part 7: Ethylene oxide sterilization residuals.	2008
ISO	10993-12	Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials	2021
Sterilization			
EN ISO	11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices (= ISO 11135:2014)	2014
ISO	11135	Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices (= EN ISO 11135:2014/ A1:2019)	2014 / Amd. 1:2018
EN	556-1	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.	2001
EN ISO	11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (=ISO 11607-1: 2019)	2020
EN ISO	11607-1	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (=ISO 11607-1: 2019)	2020 / Amd A11:2022
EN ISO	11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (= ISO 11607-2:2019)	2020
EN ISO	11607-2	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly process	2020 / Amd A11:2022
ISO	14644-1	Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration.	2015
ISO	14644-2	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration.	2015
ISO	11737-1	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	2018 +A1:2021
ISO	11737-2	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	2019
ISO	11138-1	Sterilization of health care products — Biological indicators — Part 1: General requirements	2017
ISO	11138-2	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	2017
EN ISO	14937	Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009).	2010
ISO	17665	Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	2024
ISO	19227	Implants for surgery - Cleanliness of orthopedic implants - General requirements.	2018
DIN	58953-6	Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized	2023
ASTM	F1929-23	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	2023
DIN EN	868-5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods; German version EN 868-5:2018	2019
Horizontal standards			

Standard	No.	Title	Edition
EN ISO	13485	Medical devices -- Quality management systems -- Requirements for regulatory purposes (Annexes ZA, ZB, ZC, ZD and ZE).	2016 +A11:2021
EN ISO	15223-1	ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	2021
EN ISO	20417	Medical Devices-Information to be supplied by the manufacturer. (=> ISO 20417:2021)	2021
EN ISO	14971	Medical devices -- Application of risk management to medical devices	2019/A11:2021
ISO/TR	24971	Medical Devices - Guidance on the application of ISO 14971.	2020
ISO	1942	Dentistry - Vocabulary	2020
ISO	21531	Dentistry - Graphical symbols for dental instruments	2009
ISO	2859-1	Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection	1999