



Food and Drug Administration
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December 18, 2015

Tri Dental Implants Int. AG
c/o Ms. Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K151916

Trade/Device Name: TRI[®] Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: November 13, 2015
Received: November 16, 2015

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Tina Kiang -
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for Erin I. Keith, M.S.

Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number

K151916

Device Name

TRI[®] Dental Implant System

Indications for Use (*Describe*)

The TRI[®] Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI[®] Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.

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

TRI Dental Implants Int. AG

TRI[®] Dental Implant System

December 18, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	TRI Dental Implants Int. AG Lindenstrasse 14 Baar CH-6340 Switzerland Telephone: +41 32 510 1606 Fax: +41 32 510 1601
Official Contact	Sandro Venanzoni, Chief Technology Officer
Representative/Consultant	Linda K Schulz, BSDH, RDH Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	TRI [®] Dental Implant System
Common Name	Endosseous dental implant
Classification Name	Endosseous Dental Implant
Classification Regulations	21 CFR 872.3640, Class II
Product Code	DZE, NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

The primary predicate for the TRI[®]-Narrow and TRI[®]-Vent implants is:
K101880, Tapered Screw-Vent[®] T Implant and Tapered Screw-Vent[®] P Implant, Zimmer Dental, Inc.

The primary predicate for the TRI[®]-Octa implants is:
K012757, ITI[®] Dental Implant System, Straumann USA.

The primary predicate for TRI[®]-Dental Implant System abutments is:
K083496, CAMLOG Implant System Modified Implants and Abutments, Altatec GmbH.

Reference Predicates:

K101545, Genesis Implant System, Keystone Dental;
K113779, CONELOG Implant System, Altatec GmbH;
K072570, NobelActive Multi-Unit Abutment, Nobel Biocare AB; and
K092035, Bicon Implants with a 2.5 mm Internal Connection, Bicon, LLC.

INTENDED USE

The TRI[®] Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI[®] Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading.

TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.

DEVICE DESCRIPTION

The TRI-Narrow and TRI-Vent implants are root form endosseous dental implants. They are available with two collar options, blasted or machined. TRI-Narrow is available in one implant diameter (3.3 mm) and three lengths (11.5, 13, and 16 mm). TRI-Narrow abutments include all abutment options with the exception of the Gingiva Former and the angled Screw Retained Abutment.

TRI-Vent is available in three implant diameters (3.75, 4.1 and 4.7 mm) and six lengths (6.5, 8, 10, 11.5, 13, and 16 mm). Only the 4.1 mm and 4.7 mm diameter implant bodies are available in the 6.5 mm length. All three TRI-Vent implant diameters have the same platform diameter (3.5 mm). TRI-Vent abutments include Healing Collar, Straight Temporary PEEK Abutment, Straight and 20° Angled Abutments, Straight and 30° Angled Screw Retained Abutment, Ball Abutment, PEEK Gingiva Former, Straight and 15° Angled Contoured Abutment, Gold-castable Abutment, Screw- retained Abutment, Ball Abutment, and applicable abutment fixation screws.

The TRI-Octa implants are root form endosseous dental implants. They have a pink, transgingival collar. TRI-Octa is available in three implant diameters (3.75, 4.1 and 4.7 mm) and six lengths (6.5, 8, 10, 11.5, 13, and 16 mm). Only the 4.1 mm and 4.7 mm diameter implant bodies are available in the 6.5 mm length. All three TRI-Octa implant diameters have the same platform diameter (4.8 mm). TRI-Octa abutments include Healing Collar, Straight PEEK Temporary Abutment, Straight and 20° Angled Abutments, Straight Screw Retained Abutment, Ball Abutment, and applicable abutment fixation screws..

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: sterilization validation 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*, ISO 11137-2 *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose*, 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*, ISO 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*; biocompatibility evaluation and testing according to ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, and ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*; engineering dimensional analysis, and static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*.

EQUIVALENCE TO MARKETED DEVICE

The subject device is substantially equivalent in indications and design principles predicate devices shown above. Below are summary tables showing technical comparison between the subject device and the primary predicate devices.

Device Comparison – Implants

Comparison	Subject Device	Primary Predicate Devices	
	TRI Dental Int. AG TRI [®] Dental Implant System K151916	Zimmer Dental Inc. Tapered Screw-Vent [®] T Implant and Tapered Screw-Vent [®] P Implant K101880	Straumann USA ITI [®] Dental Implant System K012757
Indications for Use	The TRI [®] Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI [®] Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.	The Tapered Screw-Vent [®] T Implants are designed for use in the maxilla or mandible for immediate loading or for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. Immediate loading is indicated when there is good primary stability and an appropriate occlusal load. The Tapered Screw-Vent [®] P Implants are designed for use in the maxilla or mandible for loading after a conventional healing period. Implants may be used to replace one or more missing teeth.	ITI [®] tapered implants are intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.
Implant Design			
TRI-Narrow			
Implant Diameter (mm)	3.3	3.3, 3.7, 4.1, 4.7, 6.0	
Platform Diameter (mm)	3.2	3.5, 4.5, 5.7	
Length (mm)	11.5, 13, 16	8, 10, 11.5, 13, 16	
Connection	Internal	Internal	
TRI-Vent			
Implant Diameter (mm)	3.75, 4.1, 4.7	3.3, 3.7, 4.1, 4.7, 6.0	
Platform Diameter (mm)	3.5	3.5, 4.5, 5.7	
Length (mm)	6.5, 8, 10, 11.5, 13, 16	8, 10, 11.5, 13, 16	
Connection	Internal	Internal	
TRI-Octa			
Implant Diameter (mm)	3.75, 4.1, 4.7		3.3, 4.1, 4.8
Platform Diameter (mm)	4.8		3.5, 4.8, 6.5
Length (mm)	6.5, 8, 10, 11.5, 13, 16		6, 8, 10, 12, 14
Connection	Internal		Internal
Material			
Implant	Titanium Alloy	Titanium Alloy	CPTi

Device Comparison – Abutments

Comparison	Subject Device	Primary Predicate Device
	TRI Dental Int. AG TRI [®] Dental Implant System K151916	Altatec GmbH CAMLOG Implant System Modified Implants and Abutments K083496
Indications for Use	The TRI [®] Dental Implant System is intended for placement in the bone of the maxillary or mandibular arch for the rehabilitation of edentulous and partially edentulous patients. TRI [®] Dental Implant System allows for one and two-stage surgical procedures. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and with appropriate occlusal loading. TRI Dental Implant System 6.5 mm implants are intended for delayed loading only.	Camlog Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. Camlog Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
Designs		
Prosthesis Attachment	Screw-retained Cement-retained	Screw-retained Cement-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit
Implant/Abutment Connection	Internal	Internal
Abutment Diameter, mm	3.3, 3.5, 4.8	3.3, 3.8, 4.3, 5.0, 6.0
Abutment Angle	Straight, up to 30°	Straight, up to 20°
Materials		
Temporary Abutment	Titanium Alloy, PEEK	PEEK
Gold Abutment	Gold alloy	Gold alloy
Abutment	Titanium Alloy	Titanium Alloy, Zirconia
Healing Cap	Titanium Alloy	NA
Abutment Screw	Titanium Alloy	Titanium Alloy

In addition to the identified primary predicates, the reference predicates all have a similar intended use as they are for placement in the maxilla or mandible for restoration of chewing function by support of a prosthetic component such as crowns and bridges.

TRI-Narrow and TRI-Vent implants have a similar bone level design, tapered internal connection, and range of sizes as K101880. TRI-Octa implants have a similar trans-gingival design, tapered internal connection and range of sizes as K012757 and K101545. Smaller length of the TRI-Vent as compared to primary predicate K101880 (6.5mm length) is supported by the reference predicate K092035 which contained a 4.0x5.0 implant body. The 16mm length is supported by the primary predicates and, for TRI-Octa by the reference predicates K101545 and K113779. All three implant designs have the same materials used for implant body in the primary predicate K101880 and for the abutments in primary predicates K083496 and reference predicate K072570. Subject device abutment designs are equivalent to the primary predicate K083496. The differences are supported by the reference predicates K113779 and K072570. The primary predicate K083496 does not include pink anodization for optimal esthetics. The pink anodization of the transmucosal collar of the submission device is included in the reference predicate K101545. The primary predicate K083496 does not include a multi-unit abutment, this is included in the

reference predicate K072570.

The performance data included in this submission demonstrate substantial equivalence to the predicate devices with respect to any differences identified. The fatigue testing provided under ISO 14801 demonstrates that the increased abutment angulation is substantially equivalent to the identified predicates with respect to performance. The surface area analysis demonstrates that the smallest diameter/shortest length combinations of the submission device are substantially equivalent to the identified reference predicate K092035 with respect to surface area available for osseointegration. Slight differences in material composition, surface treatment, or manufacturing exposures are demonstrated substantially equivalent by biocompatibility testing.

CONCLUSION

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

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.