January 6, 2020

Medentika GmbH
% Jennifer Jackson
Director, Regulatory Affairs
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01801

Re: K191123
Trade/Device Name: Multi-unit Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: December 4, 2019
Received: December 5, 2019

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191123

Device Name:

Multi-unit Abutments

Indications for Use *(Describe)*

Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

Multi-unit Abutments are used for the restoration of the following dental implant systems:

Medentika series	Implant system	Implant diameter	Platform diameter
EV-Series	Dentsply® Implants - ASTRA TECH OsseoSpeed®	3.6, 4.2, 4.8	3.6, 4.2, 4.8
F-Series	Nobel Biocare NobelActive - NobelReplace Conical	3.5, 4.3, 5.0	NP 3.5, RP 4.3/5.0
H-Series	Biomet 3i - Certain	3.25, 4.0	3.4, 4.1
L-Series	Straumann - Bone Level	3.3, 4.1, 4.8	3.3, 4.1, 4.8
N-Series	Straumann - Soft Tissue Level	4.1, 4.8	4.8, 6.5
R-Series	Zimmer Dental Tapered Screw-vent	3.3, 3.7, 4.1, 4.7	3.5, 4.5

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter's Contact Information

Submitter:	Straumann USA, LLC 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052
	On the behalf of:
	Medentika GmbH Hammweg 8-10 76549 Hügelsheim, Germany
Contact Person:	Jennifer M. Jackson, MS Director of Regulatory Affairs Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Olivier Russo Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number : +41 61 965 1260
Date of Submission:	January 6, 2020

Name of the Device

Trade Names:	Multi-unit Abutments
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Classification:	II
Product Code(s):	NHA
Classification Panel:	Dental

Predicate Device(s)

Primary Predicate:

- K171757 – Straumann Screw Retained Abutments

Reference Devices:

- K142167 – Medentika Abutment System
- K172798 – Straumann CARES Abutments CoCr
- K170838 – Medentika CAD/CAM TiBases
- K162890 – BLT 02.9mm SC, SLA or SLActive, RXD, Loxim, SC Closure Cap and Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutment
- K180564 – Medentika Abutment System, Medentika CAD/CAM Abutments, Medentika CAD/CAM TiBases

Device Description

The proposed Multi-unit Abutments are dental abutments, which are intended to be screwed onto osseointegrated dental implants to provide support for prosthetic suprastructures on the gingival level. Multi-unit abutments can be used in combination with screw-retained multi-unit dental prosthetics, e.g. bridges and bars, which are used to reconstruct the function and aesthetics of lost teeth. Multi-unit abutments are very similar to the already FDA-cleared Straumann Screw-Retained Abutment System. Multi-unit abutments are available as straight abutments, which have an integrated thread and can be screwed directly into the implant, or as angled abutments, which can be screwed onto the implant with the corresponding abutment screw. All models of Multi-unit abutments have a universal interface for a variety of pre-fabricated prosthetic parts, e.g. Multi-unit caps, which become part of the superstructure and ensure a low-tension screw connection of the multi-unit prosthetics.

The Multi-Unit caps or base are used in conjunction with the Multi-Unit Abutment. The Multi-Unit Abutment is considered the bottom half of a two-piece abutment and the Multi-Unit Caps or Multi-Unit Titanium base are considered the top half of the two-piece abutment.

Multi-unit Abutments exist in two model types: straight multi-unit abutments without rotational indexing with various gingival heights and platform diameters and angled multi-unit abutments with rotary indexing with various gingival heights and platform diameters.

Intended Use

The Multi-unit Abutments are directly screwed into the implant and have a universal mounting on the face side for various additional prosthetic parts. The bridge or bar elements are produced to fit to the prosthetic parts by which they are screwed onto the Multi-unit Abutments.

Indications for Use

Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.

Multi-unit Abutments are used for the restoration of the following dental implant systems:

Medentika series	Implant system	Implant diameter	Platform diameter
EV-Series	Dentsply® Implants - ASTRA TECH OsseoSpeed®	3.6, 4.2, 4.8	3.6, 4.2, 4.8
F-Series	Nobel Biocare NobelActive - NobelReplace Conical	3.5, 4.3, 5.0	NP 3.5, RP 4.3/5.0
H-Series	Biomet 3i - Certain	3.25, 4.0	3.4, 4.1
L-Series	Straumann - Bone Level	3.3, 4.1, 4.8	3.3, 4.1, 4.8
N-Series	Straumann - Soft Tissue Level	4.1, 4.8	4.8, 6.5
R-Series	Zimmer Dental Tapered Screw-vent	3.3, 3.7, 4.1, 4.7	3.5, 4.5

Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in Table 1. The reference device K162890 is included for adoption of the sterilization validation. K180564 is referenced in the submission to support the MRI compatibility of the subject devices.

Feature	Subject Device	Predicate Device	Reference Devices			Equivalence discussion
	Medentika Multi-unit Abutments	*K171757 - Straumann Screw Retained Abutments*	*K142167- Medentika Abutment System*	*K172798 - Straumann CARES Abutments CoCr*	*K170838 - Medentika CAD/CAM TiBases*	
Indications for use	Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient. Multi-unit Abutments are used for the restoration of the following dental implant systems (Implant System / Series / Implant diameter / Platform diameter): Dentsply® Implants - ASTRA TECH OsseoSpeed® / EV-Series / Diameter 3.6, 4.2, 4.8 / Platform 3.6, 4.2, 4.8 Nobel Biocare NobelActive - NobelReplace Conical / F-Series / Diameter 3.5, 4.3, 5.0 / Platform NP 3.5, RP 4.3/5.0 Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0 / Platform 3.4, 4.1 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 / Platform 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series /	The Straumann® Screw Retained Abutments are indicated to be placed into the implants of the Straumann® Dental Implant System to provide support for prosthetic reconstructions such as crowns, bridges and bars. The final processed devices have the purpose of restoring chewing function. Straumann® Screw Retained Abutments are indicated for screw-retained restorations.	Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Abutments are compatible with the following implant systems: Implant System/Series/Implant Diameters (mm) Nobel Biocare Replace Select/E-Series/3.5, 4.3, 5.0, 6.0 Nobel Biocare Nobel Active/F-Series/3.5, 4.3, 5.0 Biomet 3i Osseotite Certain/H-Series/3.25, 4.0, 5.0 Biomet 3i Osseotite/ I-Series/3.25, 3.75, 4.0, 5.0 Nobel Biocare Branemark/K-Series/3.3, 3.75, 4.0, 5.0 Straumann Bone Level/L-Series/3.3, 4.1, 4.8	The Straumann® CARES® Abutments CoCr are indicated for single tooth replacement and multiple tooth restorations. The prosthetic restoration can be cemented or directly veneered/screw-retained.	Medentika CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. Implant System Compatibility/Series/Implant Diameter (mm)/Platform Diameter (mm) Nobel Biocare Replace Select/E-Series/3.5, 4.3, 5.0, 6.0/3.5, 4.3, 5.0, 6.0 Dentsply Implants/ASTRA TECH OsseoSpeed EV/EV-Series/3.6, 4.2, 4.8, 5.4/3.6, 4.2, 4.8, 5.4 Nobel Biocare Nobel Active/F-Series/3.5, 4.3, 5.0/3.5, 3.9 (4.3), 3.9 (5.0) Biomet 3i Osseotite Certain/H-Series/3.25, 4.0, 5.0/3.4, 4.1, 5.0 Biomet 3i Osseotite/ I-Series/3.25, 3.75, 4.0, 5.0/3.4, 4.1, 5.0 Nobel Biocare Branemark/K-	**Equivalent** The subject device has similar indications for use as the predicate and reference devices which is to give a support for multi-unit prosthetic reconstructions such as bridges and bars. The compatible implant systems are a combination of the previously cleared compatibilities under K142167 and K170838.

Feature	Subject Device	Predicate Device	Reference Devices			Equivalence discussion
	Medentika Multi-unit Abutments	*K171757 - Straumann Screw Retained Abutments*	*K142167- Medentika Abutment System*	*K172798 - Straumann CARES Abutments CoCr*	*K170838 - Medentika CAD/CAM TiBases*	
	Diameter 4.1, 4.8 / Platform 4.8, 6.5 Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.1, 4.7 / Platform 3.5, 4.5		Straumann Standard/N-Series/3.3, 4.1, 4.8 Zimmer Tapered Screw-Vent/R-Series/3.3, 3.7, 4.1, 4.7, 6.0 Astra Tech OsseoSpeed/S-Series/3.5, 4.0, 4.5, 5.0 Dentsply Friadent Frialit/Xive/T-Series/3.4, 3.8, 4.5, 5.5 Dentsply Friadent Ankylos/Y-Series/3.5, 4.5, 5.5, 7.0		Series/3.3, 3.75, 4.0, 5.0/3.5, 4.1, 4.1, 5.1 Straumann Bone Level/L-Series/3.3, 4.1, 4.8/3.3, 4.1, 4.8 Straumann Soft Tissue Level/N-Series/3.3, 4.1, 4.8/3.5 (NNC), 4.8, 6.5 Zimmer Tapered Screw-Vent/R-Series/3.3, 3.7, 4.1, 4.7, 6.0/3.5, 4.5, 5.7 Astra Tech OsseoSpeed/S-Series/3.5, 4.0, 4.5, 5.0/3.5, 4.0, 4.5, 5.0 Dentsply Friadent Frialit/Xive/T-Series/3.4, 3.8, 4.5, 5.5/3.4, 3.8, 4.5, 5.5 Dentsply Friadent Ankylos/Y-Series/3.5, 4.5, 5.5, 7.0/3.5, 4.5, 5.5, 7.0 Medentika TiBase is intended for use with the Straumann CARES System. All digitally designed copings and/or crowns are intended to be sent to Straumann for manufactures at a validated milling center.	
Abutment Design	Straight and angled	Straight and angled	Straight and angled	Straight and angled	Straight	**Identical**

Medentika Multi-unit Abutments

510(k) Summary

Feature	Subject Device	Predicate Device	Reference Devices			Equivalence discussion
	Medentika Multi-unit Abutments	*K171757 - Straumann Screw Retained Abutments*	*K142167- Medentika Abutment System*	*K172798 - Straumann CARES Abutments CoCr*	*K170838 - Medentika CAD/CAM TiBases*	
Interface	Engaging / Non engaging	Engaging	Engaging / Non engaging	Engaging	Engaging	**Identical** to reference device K142167
Abutment angulation to Engagement feature	Straight, 17°, 30°	0°, 17°, 30°	Straight, 15°, 16°, 18°, 21°	Straight	Straight	**Equivalent** The subject device has the identical range of angulation as the primary predicate devices.
Compatible Abutment/Implant Interface Series / Implant systems Diameter(s)	Dentsply® Implants - ASTRA TECH OsseoSpeed® / EV-Series / Diameter 3.6, 4.2, 4.8 Nobel Biocare NobelActive - NobelReplace Conical / F-Series / Diameter 3.5, 4.3, 5.0 Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series / Diameter 4.1, 4.8 Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.7	Straumann Bone Level NC (Narrow CrossFit) / Diameter 3.3 Straumann Bone Level RC (Regular CrossFit) / Diameter 4.1, 4.8	Nobel Biocare Replace Select / E-Series / Diameter 3.5, 4.3, 5.0, 6.0 Nobel Biocare NobelActive / NobelReplace conical / F-Series / Diameter 3.5, 4.3, 5.0 Biomet 3i - Certain / H-Series / Diameter 3.25, 4.0, 5.0 Biomet 3i Osseotite/ I-Series / Diameter 3.25, 3.75, 4.0, 5.0 Nobel Biocare Branemark – K Series / Diameter 3.3, 3.75, 4.0, 5.0 Straumann - Bone Level / L-Series / Diameter 3.3, 4.1, 4.8 Straumann - Soft Tissue Level / N-Series / Diameter 3.3, 4.1, 4.8	Straumann Bone Level NC (Narrow CrossFit), and RC (Regular CrossFit) Straumann Soft Tissue Level RN (Regular Neck), WN (Wide Neck)	Abutments are compatible with the following implant systems: Nobel Biocare Replace™ Select E-Series 3.5, 4.3, 5.0, 6.0 Dentsply®Implants/ASTRA TECH OsseoSpeed® EV EV-Series 3.6, 4.2, 4.8, 5.4 Nobel Biocare NobelActive™/NobelReplace conical F-Series 3.5, 4.3, 5.0 Biomet 3i Osseotite® Certain® H-Series 3.25, 4.0, 5.0 Biomet 3i Osseotite® I-Series 3.25, 3.75, 4.0, 5.0 Nobel Biocare Brånemark K-Series 3.3, 3.75, 4.0, 5.0 Straumann Bone Level L-Series	**Equivalent** The compatible implant systems are a combination of the previously cleared compatibilities under K142167 and K170838. Dentsply® Implants - ASTRA TECH OsseoSpeed® / EV-Series is part of the reference device K170838, complementary performance testing was performed and demonstrated equivalence.

Feature	Subject Device	Predicate Device	Reference Devices			Equivalence discussion
	Medentika Multi-unit Abutments	*K171757 - Straumann Screw Retained Abutments*	*K142167- Medentika Abutment System*	*K172798 - Straumann CARES Abutments CoCr*	*K170838 - Medentika CAD/CAM TiBases*	
			Zimmer Dental Tapered Screw-vent / R-Series / Diameter 3.3, 3.7, 4.1, 4.7, 6.0 Astra Tech OsseoSpeed S –Series / Diameter 3.5, 4.0, 4.5, 5.0 Dentsply Friadent Frialit/Xive T -Series / Diameter 3.4, 3.8, 4.5, 5.5 Dentsply Friadent Ankylos Y –Series / Diameter 3.5, 4.5, 5.5, 7.0		3.3, 4.1, 4.8 Straumann Standard N-Series 3.3, 4.1, 4.8 Zimmer Tapered Screw-Vent® R-Series 3.3, 3.7, 4.1, 4.7, 6.0 Astra Tech OsseoSpeed™ S-Series 3.5/4.0, 4.5/5.0 Dentsply Friadent® Frialit/XiVE® T-Series 3.4, 3.8, 4.5, 5.5 Dentsply Friadent® Ankylos® Y-Series 3.5, 4.5, 5.5, 7.0 Medentika TiBase is intended for use with the Straumann® CARES® System.	
Material of Abutment (bottom half of two-piece abutment)	Ti6Al4V, medical grade 5, conforming ASTM F 136	Titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11	Ti6Al4V, medical grade 5, conforming ASTM F 136	Cobalt-chromium alloy	Ti6Al4V, medical grade 5, conforming ASTM F 136	**Equivalent** The subject device uses the type of material as the reference devices K142167 and K170838
Gingival Heights	GH 0.6 to GH 5.5 mm	GH 1.0 to GH 5.5 mm	GH 0.5 to GH 5.5 mm	Not applicable Gingiva Height is defined/designed by the dentist using CARES Visual	Not applicable, Gingiva Height is defined/designed by the dentist	**Equivalent** The subject device has a similar range of Gingival Height as the predicate and reference devices

Feature	Subject Device	Predicate Device	Reference Devices			Equivalence discussion
	Medentika Multi-unit Abutments	*K171757 - Straumann Screw Retained Abutments*	*K142167- Medentika Abutment System*	*K172798 - Straumann CARES Abutments CoCr*	*K170838 - Medentika CAD/CAM TiBases*	
Restoration	Multi-Unit restorations	Single and Multi-Unit restorations	Single and Multi-Unit restorations	Single and Multi-Unit restorations	Single restorations	**Identical** The subject device
Material of screws	Ti6Al4V, medical grade 5, conforming ASTM F 136	Titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11	Ti6Al4V, medical grade 5, conforming ASTM F 136	Titanium-6aluminum-7niobium alloy (TAN) conforming to ISO 5832-11	Ti6Al4V, medical grade 5, conforming ASTM F 136	**Equivalent** The subject device uses the type of material as the reference devices K142167 and K170838
Material of Multi-unit Base or Cap (top half of two-piece abutment)	Titanium Gold Cobalt Chromium	Titanium Gold	Not applicable	Not applicable	Not applicable	**Equivalent** The subject device uses the type of material as the reference devices K171757 and K172798
Sterility	Delivered sterile	Delivered sterile	Delivered non sterile	Delivered non sterile	Delivered non sterile	**Identical** The subject device is provided sterile which is identical to the primary predicate K171757
Sterilization by end user	No	No	Yes	Yes	Yes	**Identical** Identical to primary predicate K171757
Packaging	Medical grade polyethylene blister with a sealing lid	Medical grade polyethylene blister with a sealing lid	Medical grade polyethylene blister with a sealing lid	Poly Bag for the abutment and Medical grade polyethylene blister with a sealing lid for the screw	Plastic box	**Equivalent** The subject device uses a similar type of packaging as the predicate device

Table 1 – Technological Characteristics

Performance Testing

Dynamic fatigue and static strength tests were conducted according to ISO 14801:2016 and 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 demonstrated that the Multi-unit Abutments are equivalent to the predicate and reference devices. The tests were conducted in ambient air.

According to the FDA guidance entitled "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"", dated June 16, 2016, the subject abutments will be in contact with tissue/bone/dentin and are external communicating devices intended for more than 30 days of patient contact. Most of the subject device materials are equivalent to the predicate and reference device materials (K171757 and K142167). There is a difference in the manufacturing process for the CoCr cap compared to the reference predicate (K172798) which was addressed through cytotoxicity testing according to ISO 10993-5.

The subject device Multi-unit Abutments are provided sterile via gamma irradiation. A sterility assurance level (SAL) of 10^{-6} had been validated in accordance with *ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05.*

The subject devices will not be marketed as non-pyrogenic. The method used to make the determination that the device meets pyrogen limit specifications is LAL Endotoxin Analysis. The testing limit is 20 EU/device.

The sterilization process for the multi-unit prosthetic components and bridge screws, as recommended in the labeling, was validated according to applicable recommendations in the FDA guidance document "*Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, issued on March 17, 2015"*.

Conclusion

The documentation submitted in this premarket notification demonstrates the Multi-unit Abutments are substantially equivalent to the primary predicate and reference devices.