DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 15, 2017

Medentika GmbH
% Jennifer M. Jackson, MS
Director, Regulatory Affairs & Quality
Straumann USA, LLC
60-100 Minuteman Road
Andover, Massachusetts 01810

Re: K170838
Trade/Device Name: Medentika CAD/CAM TiBases
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: August 15, 2017
Received: August 16, 2017

Dear Jennifer M. Jackson, MS:

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 (DICE) 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 (DICE) 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,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170838

Device Name

Medentika CAD/CAM TiBases

Indications for Use *(Describe)*

Medentika TiBase 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	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Dentsply® Implants/ASTRA TECH OsseoSpeed® EV	EV	3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8, 5.4
Nobel Biocare NobelActive	F	3.5, 4.3, 5.0	3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite Certain	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Branemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann / Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann / Soft Tissue Level	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed	S	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
Dentsply Friadent Frialit/XiVE	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Dentsply Friadent Ankylos	Y	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 manufacture at a validated milling center.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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K170838

510(k) Summary

Submitter

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Date Prepared: 15 Sep 2017

Device

Trade Name:	Medentika CAD/CAM TiBases
Common Name:	Endosseous dental implant abutment
Classification Name:	Endosseous dental implant abutment (21 CFR 872.3630)
Regulatory Class:	II
Product Code:	NHA

Predicate Device

Primary Predicate:

K150203 – Medentika CAD/CAM Abutments, Medentika GmbH

Reference Predicates:

K142890 – Straumann® CARES® Variobase™ Abutments, Institut Straumann AG

K051705 – IPS e.max® CAD / IPS e.max ZIRCAD, Ivoclar Vivadent, Inc.

K061804 – zerion®, etkon International GmbH

K162890 – Straumann BLT 02.9mm SC, SLA or SLActive, RXD, Loxim, SC Closure Cap and Healing Abutments, SC Temporary Abutments, SC Variobase Abutments, SC CARES Abutment

K130436 – Ivoclar Vivadent Multilink Hybrid Abutment Cement

Device Description

The Medentika TiBases are titanium bases to be used as the lower part of two-piece abutments. The upper part of the two-piece abutment is a CAD/CAM designed and manufactured restoration. The TiBases are provided in several models and dimensions, according to the compatible implant systems declared in the Indications for Use statement.

The design of the CAD/CAM restorations is to be carried out through the Straumann CARES Visual Plug-In for Dental Wings CAD System. The patient-specific restorations must be milled by a Straumann milling center.

This submission includes:

- New TiBases with a shorter prosthetic height (3.5mm), as follows:
  - E-Series
  - F-Series
  - H-Series
  - I-Series
  - K-Series

  - L-Series
  - N-Series
  - R-Series
  - S-Series
  - T-Series
- A new line of titanium bases (EV-Series) compatible with Dentsply® Implants/ASTRA TECH OsseoSpeed® EV implants
- The zirconia raw material (zerion®, K061804) for the CAD/CAM restorations for use on the new shorter TiBases which had been previously cleared for use with the predicate Medentika TiBases (K150203)
- An additional restoration material (IPS e.max CAD, K051705) for the CAD/CAM restorations for use on the previously cleared TiBases (K150203) and the new shorter TiBases

Indications for Use

Medentika TiBase 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	3.5, 4.3, 5.0, 6.0	3.5, 4.3, 5.0, 6.0
Dentsply® Implants/ASTRA TECH OsseoSpeed® EV	EV	3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8, 5.4
Nobel Biocare NobelActive	F	3.5, 4.3, 5.0	3.5, 3.9 (4.3), 3.9 (5.0)
Biomet 3i Osseotite Certain	H	3.25, 4.0, 5.0	3.4, 4.1, 5.0
Biomet 3i Osseotite	I	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
Nobel Biocare Branemark	K	3.3, 3.75, 4.0, 5.0	3.5, 4.1, 4.1, 5.1
Straumann / Bone Level	L	3.3, 4.1, 4.8	3.3, 4.1, 4.8
Straumann / Soft Tissue Level	N	3.3, 4.1, 4.8	3.5(NNC), 4.8, 6.5
Zimmer Tapered Screw-vent	R	3.3, 3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7
Astra Tech OsseoSpeed	S	3.5, 4.0, 4.5, 5.0	3.5, 4.0, 4.5, 5.0
Dentsply Friadent Frialit/XiVE	T	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5, 5.5
Dentsply Friadent Ankylos	Y	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 manufacture at a validated milling center.

Technological Characteristics

The subject and the primary predicate devices are two-piece abutments used as a base when fabricating a CAD/CAM restoration. The subject and primary predicate devices are based on the following same technological elements:

- design
- function
- sterilization
- packaging

The following technological differences exist between the subject and primary predicate devices:

- prosthetic height (also referred to as chimney height)
- a new line of titanium bases (EV-Series)
- an additional previously cleared restoration material, IPS e.max CAD (K051705), is being indicated for the coping/crown

Table 1 provides a comparison of the features of the subject devices to the predicate devices. The assessment of the differences is also included.

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES	
	Medentika CAD/CAM Titanium Bases	Medentika CAD/CAM Abutments **(K150203)**	Straumann CARES Variobase **(K142890)**	**EQUIVALENCE DISCUSSION**
Indications for Use	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. Abutments are compatible with the following implant systems: • E-Series: Nobel Biocare Replace Select 3.5, 4.3, 5.0, 6.0 • EV-Series: Dentsply Implants / ASTRA TECH OsseoSpeed EV 3.6, 4.2, 4.8, 5.4 • F-Series: Nobel Biocare NobelActive 3.5, 4.3, 5.0 • H-Series: Biomet 3i Osseotite Certain 3.25, 4.0, 5.0 • I-Series: Biomet 3i Osseotite 3.25, 3.75, 4.0, 5.0 • K-Series: Nobel Biocare Brånemark 3.3, 3.75, 4.0, 5.0 • L-Series: Straumann Bone Level 3.3, 4.1, 4.8 • N-Series: Straumann Standard 3.3, 4.1, 4.8 • R-Series: Zimmer Tapered Screw-Vent 3.3, 3.7, 4.1, 4.7, 6.0 • S-Series: Astra Tech OsseoSpeed 3.5/4.0, 4.5/5.0 • T-Series: Dentsply Friadent Frialit/XiVE 3.4, 3.8, 4.5, 5.5 • Y-Series: Dentsply Friadent Ankylos 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 manufacture at a validated milling center.	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. Abutments are compatible with the following implant systems: • E-Series: Nobel Biocare Replace™ Select 3.5, 4.3, 5.0, 6.0 • F-Series: Nobel Biocare NobelActive™ 3.5, 4.3, 5.0 • H-Series: Biomet 3i Osseotite Certain 3.25, 4.0, 5.0 • I-Series: Biomet 3i Osseotite 3.25, 3.75, 4.0, 5.0 • K-Series: Nobel Biocare Brånemark 3.3, 3.75, 4.0, 5.0 • L-Series: Straumann Bone Level 3.3, 4.1, 4.8 • N-Series: Straumann Standard 3.3, 4.1, 4.8 • R-Series: Zimmer Tapered Screw-Vent 3.3, 3.7, 4.1, 4.7, 6.0 • S-Series: Astra Tech OsseoSpeed 3.5/4.0, 4.5/5.0 • T-Series: Dentsply Friadent Frialit/XiVE 3.4, 3.8, 4.5, 5.5 • Y-Series: Dentsply Friadent Ankylos 3.5, 4.5, 5.5, 7.0 Medentika TiBase is intended for use with the Straumann® CARES® System.	The Straumann® Variobase™ Abutment is a titanium base placed onto Straumann dental implants to provide support for customized prosthetic restorations. Straumann® Variobase™ Abutments are 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.	**Equivalent** The difference in the Indications For Use statements is related to addition of the subject devices. The basic indication of providing support for CAD/CAM prostheses is identical. All devices are CAD/CAM abutment designs to be used as a base when fabricating a patient-specific restoration.

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES	
	Medentika CAD/CAM Titanium Bases	Medentika CAD/CAM Abutments **(K150203)**	Straumann CARES Variobase **(K142890)**	**EQUIVALENCE DISCUSSION**
Implant / Abutment Diameter(s)	• E-Series: Nobel Biocare Replace Select 3.5, 4.3, 5.0, 6.0 • EV-Series: Dentsply Implants / ASTRA TECH OsseoSpeed EV 3.6, 4.2, 4.8, 5.4 • F-Series: Nobel Biocare NobelActive 3.5, 4.3, 5.0 • H-Series: Biomet 3i Osseotite Certain 3.25, 4.0, 5.0 • I-Series: Biomet 3i Osseotite 3.25, 3.75, 4.0, 5.0 • K-Series: Nobel Biocare Brånemark 3.3, 3.75, 4.0, 5.0 • L-Series: Straumann Bone Level 3.3, 4.1, 4.8 • N-Series: Straumann Standard 3.3, 4.1, 4.8 • R-Series: Zimmer Tapered Screw-Vent 3.3, 3.7, 4.1, 4.7, 6.0 • S-Series: Astra Tech OsseoSpeed 3.5/4.0, 4.5/5.0 • T-Series: Dentsply Friadent Frialit/XiVE 3.4, 3.8, 4.5, 5.5 • Y-Series: Dentsply Friadent Ankylos 3.5, 4.5, 5.5, 7.0	• E-Series: Nobel Biocare Replace Select 3.5, 4.3, 5.0, 6.0 • F-Series: Nobel Biocare NobelActive 3.5, 4.3, 5.0 • H-Series: Biomet 3i Osseotite Certain 3.25, 4.0, 5.0 • I-Series: Biomet 3i Osseotite 3.25, 3.75, 4.0, 5.0 • K-Series: Nobel Biocare Brånemark 3.3, 3.75, 4.0, 5.0 • L-Series: Straumann Bone Level 3.3, 4.1, 4.8 • N-Series: Straumann Standard 3.3, 4.1, 4.8 • R-Series: Zimmer Tapered Screw-Vent 3.3, 3.7, 4.1, 4.7, 6.0 • S-Series: Astra Tech OsseoSpeed 3.5/4.0, 4.5/5.0 • T-Series: Dentsply Friadent Frialit/XiVE 3.4, 3.8, 4.5, 5.5 • Y-Series: Dentsply Friadent Ankylos® 3.5, 4.5, 5.5, 7.0	3.3, 4.1 and 4.8 mm	**Equivalent** The subject device diameters are within the range of diameters for the primary predicate devices, so that no new concern is raised.
Implant-to-Abutment Connection / Compatible implant systems	Nobel Biocare Replace™ Select Dentsply® Implants/ASTRA TECH OsseoSpeed® EV EV-Series Nobel Biocare NobelActive™ Biomet 3i Osseotite® Certain® Biomet 3i Osseotite® Nobel Biocare Brånemark Straumann Bone Level Straumann Standard Zimmer Tapered Screw-Vent® Astra Tech OsseoSpeed™ Dentsply Friadent® Frialit/XiVE®	Nobel Biocare Replace™ Select Nobel Biocare NobelActive™ Biomet 3i Osseotite® Certain® Biomet 3i Osseotite® Nobel Biocare Brånemark Straumann Bone Level Straumann Standard Zimmer Tapered Screw-Vent® Astra Tech OsseoSpeed™ Dentsply Friadent® Frialit/XiVE® Dentsply Friadent® Ankylos®	NNC (Narrow Neck CrossFit), RN (Regular Neck), WN (Wide Neck), NC (Narrow CrossFit), RC (Regular CrossFit)	**Equivalent** Most of the connection styles of the subject devices are within the range of connections of the primary predicate devices. The new connection has been assessed through fatigue testing.

	SUBJECT DEVICE	PRIMARY PREDICATE	REFERENCE DEVICES	
	Medentika CAD/CAM Titanium Bases	Medentika CAD/CAM Abutments **(K150203)**	Straumann CARES Variobase **(K142890)**	**EQUIVALENCE DISCUSSION**
Prosthetic Height(s)	3.5 mm and 5.5 mm	4.0 mm and 5.5mm	3.5 mm	**Equivalent** The prosthetic height of the subject devices is the same as cleared for the predicate and reference devices.
Material of abutment	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Titanium-aluminum-vanadium alloy Ti-6Al-4V	Titanium-Aluminum-Niobium alloy (Ti-6Al-7Nb)	**Equivalent** All devices are made of titanium alloy. The subject devices are made of the same titanium alloy as the primary predicate device.
Material of restoration	Zirconia IPS e.max CAD	Zirconia	Acrylics (temporary) Zirconia (permanent) IPS e.max CAD (permanent) CoCr (permanent)	**Equivalent** The materials indicated for the subject devices are within the range of materials cleared for use with the predicate devices.
Cement used in device performance testing	Multilink Hybrid Abutment Cement, cleared by FDA under K130436	Multilink Hybrid Abutment Cement, cleared by FDA under K130436		**Identical**
Cement to fix patient-specific coping to TiBase according to IFU	Multilink Hybrid Abutment Cement, cleared by FDA under K130436	Multilink Hybrid Abutment Cement, cleared by FDA under K130436		**Identical**
Restoration Angulation(s)	Up to 30°	Up to 30°	Up to 30°	**Identical**
CAD/CAM System	Straumann CARES System	Straumann CARES System	Straumann CARES System	**Identical**
Sterility	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	Delivered non-sterile; to be sterilized by user	**Identical**
Sterilization by end user	Moist heat sterilization	Moist heat sterilization	Moist heat sterilization	**Identical**

Table 1 – Comparison between the subject and predicate devices

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the subject devices was conducted in accordance with ISO 10993-1:2009 "*Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* and the biocompatibility evaluation flow chart according 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*".

The subject devices have the identical nature of body contact, contact duration, material formulation, manufacturing processes, and sterilization methods compared to the primary predicate devices. No new issues of biocompatibility are raised for the subject devices. Therefore, no additional biocompatibility testing was required.

Sterilization Validation

Medentika titanium bases are provided non-sterile. Prior to use, sterilization is recommended. This cycle has been validated to a sterility assurance level (SAL) of 10^{-6} by the overkill method, according to ISO 17665-1 *Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1*.

Mechanical Testing

The mechanical strength of the system is demonstrated through fatigue testing performed according to ISO 14801 - *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* and the FDA document *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments*. The tested subject devices exhibit a level of performance equivalent to that reviewed for the predicate devices.

Reverse engineering dimensional analysis was conducted using OEM implant bodies, OEM abutments, and OEM abutment screws.

Conclusion

Based upon the assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.