January 7, 2019

Medentika GmbH
% Jennifer Jackson
Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K180564
Trade/Device Name: Medentika Abutment System
Medentika CAD/CAM Abutments
Medentika CAD/CAM TiBases
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 5, 2018
Received: October 9, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180564

Device Name
Medentika Abutment System

Indications for Use *(Describe)*

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 NobelActive	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
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

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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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)*
K180564

Device Name
Medentika CAD/CAM Abutments

Indications for Use *(Describe)*

Medentika Preface 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
Nobel Biocare NobelActive™	F	3.0, 3.5, 4.3, 5.0	3.0, 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 Brånemark	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 Standard	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	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 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

Medentika PreFace is intended for use with the Straumann CARES System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann CARES 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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)*
K180564

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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5 510(k) Summary

5.1 Submitter

Straumann USA, LLC (on behalf of Medentika GmbH)

60 Minuteman Road

Andover, MA 01810

Phone Number: (978) 747-2509

Fax Number: (978) 747-0023

Contact Person: Jennifer M. Jackson, MS

Director, Regulatory Affairs

Prepared By: Christopher Klaczyk

Date of Submission: January 7, 2019

Device Trade Name: Medentika Abutment System

Medentika CAD/CAM Abutments

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

5.2 Predicate Device

Predicate Devices: K170838 – Medentika CAD/CAM TiBases

K150203 – Medentika CAD/CAM Abutments

K142167 – Medentika Abutment System

Reference Predicate: None

5.3 Device Description

The subject devices comprise the metallic endosseous dental implant abutments and metallic prosthetic superstructures cleared to market in the United States as of December 15, 2017 under K170838, K150203, and K142167 by Medentika GmbH as part of the Medentika Multi-Platform System.

Medentika Multi-Platform System is an abutment system including eleven abutment designs compatible with twelve currently marketed implant systems. The abutment designs include abutments for single-tooth and multiple-tooth restoration for supporting cement-retained, screw-retained or overdenture prostheses. Platform diameters range from 3.3 mm to 7.0 mm. Corresponding implant diameters range from 3.25 mm to 7.0 mm. Angled abutment designs for connections with anti-rotational features are available in two orientations, Type 1 and Type 2. Type 1 is for abutments with the cone angle oriented toward the flat of the anti-rotational feature and Type 2 is for abutments with the cone angle oriented toward the corner or lobe of the anti-rotational feature. The maximum angle for any abutment within the eleven systems is 21°.

The 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 assessment of these devices in the MR environment has not resulted in any changes to the devices themselves. The proposed labeling change provides the parameters under which a patient having a restoration constructed using the devices of the Medentika Multi-Platform System can safely undergo an MRI scan.

The stock endossoues dental implant abutments are fabricated from titanium-aluminum-vanadium (TAV) alloy and noble metal alloys. The CADCAM abutments are fabricated from commercially pure titanium. The materials for the TiBase copings and/or crowns include zerion and IPS e.max CAD.

5.4 Indications for Use

Medentika Abutment System

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 Diameter (mm)*
Nobel Biocare Replace Select	E -Series	3.5, 4.3, 5.0, 6.0
Nobel Biocare NobelActive	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
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 CAD/CAM Abutments

Medentika Preface 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	*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
Nobel Biocare NobelActive	F	3.0, 3.5, 4.3, 5.0	3.0, 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 Standard	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	3.0, 3.5, 4.0, 4.5, 5.0	3.0, 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

Medentika PreFace is intended for use with the Straumann CARES System. All digitally designed abutemtns for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann CARES validated milling center.

Medentika CAD/CAM TiBases

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	*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 / AstraTech 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 Standard	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.

5.5 Technological Characteristics

The scope of this submission is the modification of the device labeling to include validated MRI Safety Information. The materials, processing, dimensions, packaging, sterilization, and labeling are all identical to those of the identified predicate devices. The indications for use of the subject devices are also identical to those of the identified predicate devices.

The intended use of the subject devices is expanded in that the devices are now identified as being MR Conditional.

5.6 Performance Data

The testing presented in this submission is consistent with the FDA Guidance entitled *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment dated August, 2014 and the FDA Guidance document entitled Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices* dated June 29, 2015.

For the evaluation of displacement force, testing was conducted per the deflection angle test per ASTM F2052-15, *Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment*.

For the evaluation of torsional force, testing was conducted per the procedure described by Shellock, et al. This method has been shown to be acceptable for the evaluation of torque for a metallic implant or device. According to ASTM F2213-06 (2011), *Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment*, such alternative methods are acceptable.

For the evaluation of RF-induced heating, testing was conducted per recommendations in ASTM F2182-11a, *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging*.

For the evaluation of image artifacts, testing was conducted per ASTM F2119-13, *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*.

5.7 Conclusion

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

Based upon the proposed definition of the worst-case constructs incorporating metallic implantable devices, and the physical testing of same, we have defined the following text to be used for the MRI Safety Information section of the labeling:

MR Conditional

Non-clinical testing and MRI simulations were performed to evaluate the dental implant abutment system offered by Medentika GmbH. Non-clinical testing demonstrates that these products are MR Conditional. A patient with an implant abutment from the Medentika Multi-Platform System can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, only
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg and head average SAR of 3.2 W/kg, for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the implant abutments from the Medentika Multi-Platform System are expected to produce a maximum temperature rise of 4.9°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the implant abutments from the Medentika Multi-Platform System extend approximately 10 mm from this device when imaged with a gradient echo pulse sequence and a 3 Tesla MR system