DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

Medentika GmbH
c/o Ms. Linda Schulz
Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, CA 92130

Re: K142167
Trade/Device Name: Medentika Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 21, 2015
Received: January 22, 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,

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

Enclosures

Indications for Use

510(k) Number: K142167

Device Name: 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 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

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
Medentika GmbH
Medentika Abutment System

February 19, 2015

ADMINISTRATIVE INFORMATION

Manufacturer Name	Medentika GmbH Hammweg 8-10 76549 Hügelsheim, Germany Telephone +49 (0)7229-69912-0 Fax +49 (0)7229-69912-20
Official Contact	Gerhard Polzer Head of Quality Management / Regulatory Affairs
Representative/Consultant	Linda K. Schulz Floyd G. Larson 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	Medentika Abutment System
Common Name	Endosseous dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

INTENDED USE

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

DEVICE DESCRIPTION

Medentika Abutment System is an abutment system including ten abutment designs compatible with eleven 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°.

EQUIVALENCE TO MARKETED DEVICE

K020646	Replace™ HA Coated Implant
K071370	NobelActive Internal Connection Implant
K063341	3i OSSEOTITE Certain® Dental Implants
K063286	OSSEOTITE Dental Implants
K022562	Various Brånemark System Implants – Immediate Function Indication
K062129	P.004 Implants
K130222	Straumann Dental Implant System SLActive and Roxoid Product Families
K061410	Zimmer Dental Implant System
K101732	Astra Tech Implant System
K073075	FRIADENT Implant Systems

K041509	ANKYLOS® Dental Implant System
K072570	NobelActive Multi-Unit Abutment
K093643	Multi-Unit Abutments for Straumann and Astra Tech Implant Systems
K072878	Locator Implant Anchor
K092434	2.2 mm Angled Micro ERA Dental Implant System
K120414	OsseoSpeed™ Plus
K083496	CAMLOG Implant System Modified Implants and Abutments
K080239	P.004 RC/NC Bar and Bridge Abutments Line

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included: Sterilization validation 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 ISO 17665-1,* biocompatibility testing according to ISO 10993-5 *Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity,* engineering analysis, dimensional analysis, and static and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants.*

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

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.