



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

December 1, 2015

Biodenta Swiss AG
Mr. David Eiler
Regulatory Manager
Tramstrasse 16
Berneck, St. Gallen 9442
SWITZERLAND

Re: K151295

Trade/Device Name: Biodenta Customized Abutment - Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 5, 2015
Received: November 23, 2015

Dear Mr. Eiler:

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
-S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K151295

Device Name

Biodenta Customized Abutment - Titanium

Indications for Use (Describe)

The Biodenta Customized Abutment - Titanium is 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.
The Biodenta Customized Abutment - Titanium is compatible with the following dental implant systems:

Implant Brand, Type	Implant Platform Name: Implant Diameter
Biodenta, Bone Level and Tapered	B1: 3.5 mm; B2: 4.1, 4.8, 6.0 mm
Nobel Biocare, Nobel Replace straight and tapered	NP: 3.5 mm; RP: 4.3 mm; WP: 5.0 mm; 6.0: 6.0 mm
Nobel Biocare, NobelActive	NP: 3.5 mm; RP: 4.3, 5.0 mm
Biomet 3i, Certain Internal	3.4: 3.25, 4.0 mm; 4.1: 4.0, 5.0 mm; 5.0: 5.0, 6.0 mm; 6.0: 6.0 mm
Dentsply, Astra Tech OsseoSpeed	3.5/4.0: 3.5, 4.0 mm; 4.5/5.0: 4.5, 5.0 mm
Straumann, Bone Level	NC: 3.3 mm; RC: 4.1, 4.8 mm
Zimmer, Screw Vent and Screw Vent Tapered	3.5: 3.3, 3.7, 4.1 mm; 4.5: 4.7 mm; 5.7: 6.0 mm
Biohorizons, Internal straight and tapered	3.5: 3.5, 3.8 mm; 4.5: 4.0, 4.6 mm; 5.7: 5.0, 6.0, 5.8 mm;
Osstem (Hiossen), GS and TS	Mini: 3.5 mm; Regular: 4.0, 4.5, 5.0 mm

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
PRASStaff@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."

K151295

5

510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
Fax number:	+ 41 71 747 11 12
Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	November 27, 2015
Trade / proprietary name:	Biodenta Customized Abutment - Titanium
Common name:	Endosseous dental implant abutment
Device classification name:	Endosseous Dental Implant Abutment
Product code:	NHA
Regulation number :	21 CFR 872.3630
Legally marketed device to which equivalence is claimed (predicate device):	
1. Company:	Biodenta Swiss Ag
Device name:	Biodenta Customized Abutment
510(k) number:	K110778 (primary predicate)
2. Company:	Prismark Dentalcraft, Inc
Device name:	Inclusive Titanium Abutments For Astra Tech Osseospeed Implants
510(k) number:	K100993

3. Company:	Prismark Dentalcraft, Inc
Device name:	Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark, and Nobel Biocare NobelActive Implants
510(k) number:	K142118
4. Company:	Prismark Dentalcraft, Inc
Device name:	Inclusive® Titanium Abutments, compatible with Zimmer Screw- Vent, Biomet 3i Certain, and Nobel Biocare NobelReplace Implants
510(k) number:	K142115
5. Company:	Biodenta Swiss Ag
Device name:	Biodenta Dental Implant System - Multi-Use Abutment
510(k) number:	K123491

Indications for Use:

The Biodenta Customized Abutment - Titanium is 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.

The Biodenta Customized Abutment - Titanium is compatible with the following dental implant systems:

Implant Brand, Type	Implant Platform Name: Implant Diameter
Biodenta, Bone Level and Tapered	<i>B1</i> : 3.5 mm; <i>B2</i> : 4.1, 4.8, 6.0 mm
Nobel Biocare, Nobel Replace straight and tapered	<i>NP</i> : 3.5 mm; <i>RP</i> : 4.3 mm; <i>WP</i> : 5.0 mm; <i>6.0</i> : 6.0 mm
Nobel Biocare, NobelActive	<i>NP</i> : 3.5 mm; <i>RP</i> : 4.3, 5.0 mm
Biomet 3i, Certain Internal	<i>3.4</i> : 3.25, 4.0 mm; <i>4.1</i> : 4.0, 5.0 mm; <i>5.0</i> : 5.0, 6.0 mm; <i>6.0</i> : 6.0 mm
Dentsply, Astra Tech OsseoSpeed	<i>3.5/4.0</i> : 3.5, 4.0 mm; <i>4.5/5.0</i> : 4.5, 5.0 mm
Straumann, Bone Level	<i>NC</i> : 3.3 mm; <i>RC</i> : 4.1, 4.8 mm
Zimmer, Screw Vent and Screw Vent Tapered	<i>3.5</i> : 3.3, 3.7, 4.1 mm; <i>4.5</i> : 4.7 mm; <i>5.7</i> : 6.0 mm
Biohorizons, Internal straight and tapered	<i>3.5</i> : 3.5, 3.8 mm; <i>4.5</i> : 4.0, 4.6 mm; <i>5.7</i> : 5.0, 6.0, 5.8 mm;
Osstem (Hiossen), GS and TS	<i>Mini</i> : 3.5 mm; <i>Regular</i> : 4.0, 4.5, 5.0 mm

Device Description:

Biodenta Customized Abutment - Titanium is a one-piece custom abutment made of titanium. It utilizes an Abutment Screw for abutment retention.

The upper portion is designed by a dental technician using CAD software and manufactured at Biodenta milling centers. The final cement retained restoration is constructed in the lab according to the dentist's specifications.

The Abutment and the Abutment Screw are made of biocompatible Ti-6Al-4V ELI conforming to ISO 3852-3 and ASTM F136.

Non-clinical Testing Data:

Fatigue testing was conducted according to FDA Guidance: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff. The worst-case scenario for the Biodenta Customized Abutment - Titanium and implant was tested. The results show that the Biodenta Customized Abutment - Titanium has sufficient mechanical strength for the intended clinical application. A biocompatibility assessment determined that biocompatibility testing was not necessary. Titanium has a long history of use in dental applications and Biodenta also has an established history of manufacturing titanium based dental devices.

The engineering of the Biodenta Customized Abutment - Titanium was carried out by measuring the original implant manufacturer's implants, implant analogs, abutments, and abutment screws. Compatible abutments and screws were developed based on the measurement results. An engineering and compatibility analysis was carried out to ensure that the Biodenta Customized Abutment - Titanium fits well with the original manufacturer's implants (Nobel Biocare, Nobel Replace; Nobel Biocare, NobelActive; Biomet 3i, Certain Internal; Dentsply, Astra Tech OsseoSpeed; Straumann, Bone Level; Zimmer, Screw Vent and Screw Vent Tapered; Biohorizons, Internal straight and tapered; Osstem (Hiossen), GS/TS). Additionally fatigue testing according to FDA Guidance for Industry and Staff - Class II Special Controls Guidance Document: Root- form Endosseous Dental Implants and Endosseous Dental Implant Abutments was carried out to confirm the mechanical fatigue strength of the Biodenta Customized Abutment - Titanium on the original manufacturer's implant fixture.

The Sterilization Validation was carried out according to ISO 17665-1:2006. The recommended sterilization method is provided in the Information for Use.

Equivalence to marketed device:

While the indications for use statements between the subject and predicate device are not identical, the intended use is still the same. They are all abutments intended to be compatible with a specific subset of implants to support dental restorations. Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Customized Abutment - Titanium is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

Summary Substantial Equivalence Comparison to predicate devices:

	Subject Device	Primary Predicate	Reference Predicates				
Company	Biodenta Swiss AG	Biodenta Swiss AG	Prismark Dentalcraft, Inc	Prismark Dentalcraft, Inc	Prismark Dentalcraft, Inc	Biodenta Swiss AG	Pou Yu Biotechnology Co., Ltd.
Device Name	Biodenta Customised Abutment - Titanium	Biodenta Customized Abutment	Inclusive Titanium Abutments For Astra Tech Osseospeed Implants	Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark , and Nobel Biocare NobelActive Implants	Inclusive® Titanium Abutments, compatible with Zimmer Screw-Vent, Biomet 3i Certain, and Nobel Biocare NobelReplace Implants	Biodenta Dental Implant System - Multi-Use Abutment	TDS Abutment for Friadent Xive
510(k) Number	New device	K110778	K100993	K142118	K142115	K123491	K103339
Intended use	The Biodenta Customized Abutment is 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.	The Biodenta Customized Abutment is 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. The Biodenta Customized Abutment is compatible with the following implant systems: - Internal hex systems with flat-to-flat dimensions of 1.78mm or greater: Firadent: FRIALIT Implant, XiVA Implant; 3i: Certain Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; BioHorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System; Life core: Lifecore RENOVA Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System. - Nobel Biocare Replace: NobelReplace Straight, NobelReplace Tapered Replace Select Tapered, Replace Select Straight; for the NP,RP,WPand6.0 implants. - External hex systems with flat-to-flat dimensions of 2.4 mm or greater:Nobel Bioca	The InclusiveO Titanium Abutments for Astra OsseoSpeed'M Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.	Inclusive® Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. Inclusive® Titanium Abutments are compatible with: - Straumann: Bone Level NC and RC implant sizes - Nobel Biocare: Branemark RP size implant - Nobel Biocare NobelActive NP and RP internal connection implants	Inclusive® Titanium Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. Inclusive® Titanium Abutments are compatible with: - Biomet: 3i Certain internal hex implants in 3.4, 4.1, 5.0, 6.0 mm sizes - Nobel Biocare: NobelReplace straight and tapered internal connection implants in NP, RP, WP, 6.0 mm sizes - Zimmer: Screw-Vent and Tapered Screw-Vent internal hex implants in 3.5, 4.5, 5.7 mm sizes	Biodenta Dental Implant System Multi Use Abutments are intended for terminal or intermediate abutment support for fixed or removable crown, bridgework and to retain overdentures.	TDS Abutment for Friadent Xive is 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. This device is compatible with the following implant systems which have an internal hex with flat-to-flat dimensions of 1.78mm or greater: Firadent: FRIALIT Implant, XiVA Implant; 3i: Internal Connect Type; Astra: Osseospeed Implant, Osseospeed TX Implant; BioHorizons: Internal Implant System, Tapered Internal Implant System, Single-Stage Implant System, Laserlok®3.0 implant system; Lifecore: Lifecore RENOVATM Internal Hex Implant System; Zimmer: Tapered Screw-Vent Implant System, Screw-Vent Implant System, AdVent Implant System; Osstem: GS System; Nobel Biocare: Active Implant.

	Subject Device	Primary Predicate	Reference Predicates				
Company	Biodenta Swiss AG	Biodenta Swiss AG	Prismark Dentalcraft, Inc	Prismark Dentalcraft, Inc	Prismark Dentalcraft, Inc	Biodenta Swiss AG	Pou Yu Biotechnology Co., Ltd.
Device Name	Biodenta Customised Abutment - Titanium	Biodenta Customized Abutment	Inclusive Titanium Abutments For Astra Tech Osseospeed Implants	Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark , and Nobel Biocare NobelActive Implants	Inclusive® Titanium Abutments, compatible with Zimmer Screw-Vent, Biomet 3i Certain, and Nobel Biocare NobelReplace Implants	Biodenta Dental Implant System - Multi-Use Abutment	TDS Abutment for Friadent Xive
510(k) Number	New device	K110778	K100993	K142118	K142115	K123491	K103339
Compatible implant types	<ul style="list-style-type: none"> - Dentsply, AstraTech OsseoSpeed - Biomet 3i, Certain Internal - Zimmer, Screw Vent - Nobel Biocare, NobelReplace - Nobel Biocare, NobelActive - Straumann, Bone Level - BioHorizons, Internal - Osstem, GS/TS - Biodenta, Bone Level and Tapered 	<ul style="list-style-type: none"> - Dentsply, AstraTech OsseoSpeed - Biomet 3i, Certain Internal - Zimmer, Screw Vent - Nobel Biocare, NobelReplace - Nobel Biocare, NobelActive - Straumann, Bone Level 	<ul style="list-style-type: none"> - Dentsply, AstraTech OsseoSpeed 	<ul style="list-style-type: none"> - Nobel Biocare, NobelActive - Straumann, Bone Level 	<ul style="list-style-type: none"> - Biomet: 3i Certain internal - Zimmer: Screw-Vent - Nobel Biocare: NobelReplace 	<ul style="list-style-type: none"> - Dentsply, AstraTech OsseoSpeed - Biomet 3i, Certain Internal - Zimmer, Screw Vent - Nobel Biocare, NobelReplace - Nobel Biocare, NobelActive - Straumann, Bone Level - BioHorizons, Internal - Osstem, GS/TS 	<ul style="list-style-type: none"> - Biodenta, Bone Level and Tapered
Custom Design							
maximal Abutment Angulation	30°	30°	30°	30°	30°	30°	30°
Abutment Diameter	4.5 - 15 mm	5 - 10 mm	max. 9.4 mm	max. 9.4 mm	max. 9.4 mm	4.5 - 5.0 mm	5 - 10 mm
Abutment Height	5.0 - 12.3 mm	3.0 - 7.5 mm	max 12.45 mm	max 12.45 mm	max 12.45 mm	2.0 - 5.5 mm	3.0 - 7.5 mm
Abutment fixation	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw
CAD/CAM Processing	Milled in Biodenta milling center under QSR control	Milled in Biodenta milling center under QSR control	Milled in manufact. milling center under QSR control	Milled in manufact. milling center under QSR control	Milled in manufact. milling center under QSR control	NA	Milled in manufact. milling center under QSR control



	Subject Device	Primary Predicate	Reference Predicates				
Company	<i>Biodenta Swiss AG</i>	<i>Biodenta Swiss AG</i>	<i>Prismark Dentalcraft, Inc</i>	<i>Prismark Dentalcraft, Inc</i>	<i>Prismark Dentalcraft, Inc</i>	<i>Biodenta Swiss AG</i>	<i>Pou Yu Biotechnology Co., Ltd.</i>
Device Name	<i>Biodenta Customised Abutment - Titanium</i>	<i>Biodenta Customized Abutment</i>	<i>Inclusive Titanium Abutments For Astra Tech Osseospeed Implants</i>	<i>Inclusive® Titanium Abutments compatible with: Straumann Bone Level, Nobel Biocare Branemark , and Nobel Biocare NobelActive Implants</i>	<i>Inclusive® Titanium Abutments, compatible with Zimmer Screw-Vent, Biomet 3i Certain, and Nobel Biocare NobelReplace Implants</i>	<i>Biodenta Dental Implant System - Multi-Use Abutment</i>	<i>TDS Abutment for Friadent Xive</i>
510(k) Number	<i>New device</i>	<i>K110778</i>	<i>K100993</i>	<i>K142118</i>	<i>K142115</i>	<i>K123491</i>	<i>K103339</i>
Material							
Abutment + Screw	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Sterile / Reuse							
Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile	Delivered Non Sterile
Reusable	no	no	no	no	no	no	no

(Blank Page)