K122559

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MAY 3 2013

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510(k) Summary

Owner's name:	Biodenta Swiss AG
Address:	Tramstrasse 16 9442 Berneck Switzerland
Phone:	+41 71 747 11 11
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Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	March 18, 2013
Trade / proprietary name:	Biodenta Dental Implant System – Abutments
Common name:	Endosseous dental implant abutment
Device classification name:	Abutment, Implant, Dental, Endosseous
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 Dental Implant System – Bone Level
510(k) number:	K111003
2. Company:	Biohorizons Implant Systems, Inc.
Device name:	Biohorizons Plastic Temporary Abutments
510(k) number:	K053099

3.	Company:	Zimmer Dental Inc.
	Device name:	Plastic Temporary Abutments
	510(k) number:	K092377
4.	Company:	Implant Direct LLC.
	Device name:	Spectra System Dental Implants 2008
	510(k) number:	K090234

Indications for Use:

Biodenta Dental Implant System Abutments are intended for terminal or intermediate abutment support for fixed or removable crown or bridgework.

Device Description:

The Biodenta Dental Implant System Abutments is an extension and compatible to the Biodenta Dental Implant System Bone Level (K111003) which is an integrated system of endosseous dental implants, abutments and prosthetic parts and related surgical instruments.

The Biodenta Dental Implant System Abutments includes 3 abutment types:

Temporary PEEK abutments are manufactured of biocompatible PEEK plastic and used for temporary restorations for 180 days or less. They are attached to the dental implant using an abutment screw made of titanium alloy.

Swift Abutments are manufactured of biocompatible Titanium Alloy. The Abutments are attached to the implant by screwing them directly to the implant with the integrated screw thread. The Swift Abutments are designed in order that crowns and bridges can be attached by cement retention.

Sleeve Abutments are manufactured of biocompatible Titanium Alloy. The Abutments are attached to the implant by screwing them directly to the implant with the integrated screw thread. The Sleeve abutments are designed in order that bridges can be attached by screw retention.

All Abutments are straight abutments.

Non-clinical Testing Data:

The Biodenta Dental Implant System Abutments do not include angled abutments. Following the guide "Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseus Dental Implant Abutment" (May 12, 2004) no further fatigue test was performed.

A sterilization validation according to ISO 14937:2009 and a residual moisture validation was carried out to confirm the recommended sterilization parameters and drying time.

Biocompatible raw materials have been used for manufacturing the abutments. The final products have been investigated on the chemical cleanness by an XPS analysis and on leachable cytotoxic substances (according to ISO 10993-5:2009) to determine the effects of the manufacturing process to the materials. The results demonstrate that the final products after manufacturing are considered to be biocompatible.

A risk analysis following the guide "Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseus Dental Implant Abutment" (May 12, 2004) has been carried out. The implemented mitigations measures were found being suitable to reduce the residual risks to an acceptable level.

Equivalence to marketed device:

Biodenta Swiss AG demonstrated that, for the purposes of FDA's regulation of medical devices, the Biodenta Dental Implant System Abutments is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design.

The summary table for the Substantial Equivalence Comparison to predicate devices is attached on the following page

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	Subject Device	Predicate Devices			
Device Name	Biodenta Dental Implant System - Abutments	Biodenta Dental Implant System – Bone Level K111003	Biohorizons Plastic Temporary Abutments K053099	Zimmer Dental Inc. Plastic Temporary Abutments K092377	Implant Direct LLC. Spectra System Dental Implants 2008 K090234
Intended Use					
Intended use	Biodenta Dental Implant System Abutments are intended for terminal or intermediate abutment support for fixed or removable crown or bridgework	Biodenta bone level dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations or terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.	BioHorizons Plastic Temporary Abutments are intended for short-term use of 30 days or less as a base for cemented or screw-retained crown and bridge restoration of dental implants, while esthetically contouring soft tissue.	The Plastic Temporary Abutment is intended to be used to fabricate andsupport provisional restorations that aid increating an esthetic emergence through the gingiva during the healing period and prior to final restoration. The Plastic Temporary Abutment can be used for cement-retained or screw-retained provisional restoration. The abutments can be used for single-unit and multi-unit restorations. Use of the Plastic Temporary Abutment is not to exceed one-hundred and eighty (180) days.	The Spectra-System Dental Implant 2008 system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The Dental Implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occusal load requirements.
Basic Design					
Abutment Type	Temporary & Final Abutments	Temporary & Final Abutments	Temporary Abutments	Temporary Abutments	Final Abutments
Abutment as Impression Post	Yes	No	No	No	Yes (fixture mount used as impression post and abutment)
Abutment Type	Straight Abutments	Straight & Angled Abutment	Straight Abutment	Straight & Angled Abutment	Straight Abutments
Abutment Angle	0°	0° - 15°	0°	0° - 17°	0°
Implant / Abut. Connection	Internal Hexagon	Internal Hexagon	Internal Octagon	Internal Hexagon	Internal Hexagon
Temporary Abutment Diameter	4.0 mm 6.5 mm -- --	3.5 mm 3.7 mm -- --	3.5 mm 4.5 mm 5.5 mm 6.5 mm	4.5 mm 5.5 mm 6.5 mm --	-- -- -- --
Temporary Abutment Height	9.8 mm	7.0 mm	10.5 mm	8.0 mm	--
Final Abutment Diameter	3.7 - 5.5 mm	3.5 - 6.0 mm	---	---	4.8 - 6.6 mm
Final Abutment Height	1.5 - 12 mm	5.7 - 9.8 mm	---	---	6.5 mm
Material					
Temporary Ab. Material	biocompatible PEEK	Titanium Alloy	biocompatible PEEK	biocompatible PEEK	---
Terminal Ab. Material	Titanium Alloy	Titanium Alloy	---	---	Titanium Alloy
Sterilization					
Sterilization	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Provided Non-Sterile	Provided sterile with implant packaging
Reuse	Singe use	Singe use	Singe use	Singe use	Single use

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

May 3, 2013

Mr. David Eiler
Regulatory Manager
Biodenta Swiss AG
Tramstrasse 16
Berneck, Switzerland 9442

Re: K122559
Trade/Device Name: Biodenta Dental Implant System Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 30, 2013
Received: May 1, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer -S
2013.05.03 11:27:36 -04'00' for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K122559

Device Name: Biodenta Dental Implant System Abutments

Indications for Use:

Biodenta Dental Implant System Abutments are intended for terminal or intermediate abutment support for fixed or removable crown or bridgework.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=13000879
Date: 2013.05.02 11:39:22 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122559