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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
Fax number:	+ 41 71 747 11 12
Contact person:	Mr. David Eiler, Regulatory Manager
Date summary prepared:	February 26, 2013
Trade / proprietary name:	Biodenta Dental Implant System – Multi-Use Abutment
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:	Nobel Biocare AB
Device name:	NobelActive Multi Unit Abutment
510(k) number:	K072570

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3. Company: Biomet 3i

Device name: Low Profile Abutment

510(k) number: K092341

Indications for Use:

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.

Device Description:

The Biodenta Dental Implant System - Multi-Use Abutment is an extension 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 - Multi-Use Abutment includes 0°, 18°, and 30° abutments for screw retained restorations. Each angulation is available with 2, 3, 4, and 5 mm cuff height for both Biodenta Bone Level implant platform types (B1 and B2). The angulated abutments include hexed and non-hexed versions for single unit or multi unit restorations respectively. Abutment diameters are from 4.5 - 5.0 mm.

The system includes a ball attachment abutment with a diameter of 4.5 mm and height of 5.5 mm, and temporary abutments with a diameter of 4.0 mm and height of 12.5 mm, which are to be attached onto the Multi-Use Abutment. Burn out cylinders are provided. The system includes 2 diameters of abutment and 1 diameter of prosthetic screws. Short and long impression posts for open and closed tray impression taking, and a protective cap for the Multi-Use Abutment is included.

Non-clinical Testing Data:

Fatigue testing was conducted according to FDA Guide: 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 Dental Implant System - Multi Use-Abutment and implant was tested. The results show that the Biodenta Dental Implant System - Multi Use-Abutment has sufficient mechanical strength for the intended clinical application.

Equivalence to marketed device:

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

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Summary Substantial Equivalence Comparison to predicate devices:

	Subject Device	Predicate Devices		
Company	Biodenta Swiss AG	Biodenta Swiss AG	Nobel Biocare AB	Biomet 3i
Device Name	Biodenta Dental Implant System – Multi-Use Abutment	Biodenta Dental Implant System – Bone Level	NobelActive Multi Unit Abutment	Low Profile Abutment
510(k) Number	New device	K111003	K072570	K092341
Intended use	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.	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.	NobelActive Multi Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	BIOMET 3i Low Profile Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.
Restorations	Screw retained	Screw retained & cemented	Screw retained	Screw Retained
Abutment Type	Straight & Angled	Straight & Angled	Straight & Angled	Straight & Angled
Abutment Angle	0°, 18°, 30°	0° - 15°	0°, 17°, 30°	0°, 17°, 30°
Implant to Abut. Connect	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon
Abutment fixation	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw
Compatible Implants Diameter	3.5 mm 4.1 mm 4.8 mm	3.5 mm 4.1 mm 4.8 mm	3.5 mm 4.3 mm 5.0 mm	3.25 mm 4.0 mm 5.0 mm 6.0 mm
Abutment cuff height	2.0 – 5.0 mm (0°) 2.2 – 5.2 mm (18°) 2.0 – 5.0 mm (30°)	5.7 – 9.8 mm	1.5 – 4.5 mm (0°) 2.5 – 3.5 mm (17°) 3.5 – 4.5 mm (30°)	1.0 – 4.0 mm (0°) 2.0 – 4.0 mm (17°) 3.0 – 5.0 mm (30°)
Abutment Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Sterilization	Delivered non sterile	Delivered non sterile	Delivered non sterile	Delivered non sterile
Reusable	No	No	No	No

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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 30, 2013

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

Re: K123491
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: May 15, 2013
Received: May 16, 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,

Susan Runner, DDS, MA

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=1300087950
Date: 2013.05.30 11:26:12 -04'00'

Kwame Ulmer, M.S.
Acting 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): K123491

Device Name: Biodenta Dental Implant System – Multi-Use Abutment

Indications for Use:

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.

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)

Susan Runner, DDS, MA

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=1300087950
Date: 2013.05.30 09:59:13 -04'00'

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

510(k) Number: K123491