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 Eller, Regulatory Manager
Date summary prepared: April 8, 2011
Trade / proprietary name: Biodenta Dental Implant System - Bone Level
Common name: Endosseous dental implant
Device classification name: implant, endosseous, root-form
Product code: DZE
Regulation number: 21 CFR 872.3640
Subsequent Product Code: NHA (Regulation number: 21 CFR 872.3630)
Legally marketed device to which equivalence is claimed (predicate device):
Company: Biodenta Swiss AG
Device name: Biodenta Dental Implant System
510(k) number: K093630
Company: Nobel Biocare Ab
Device name: Nobelactive Internal Connection Implant
510(k) number: K071370
Indications for Use:
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.

Device Description:
The Biodenta Dental Implant System – Bone Level is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, abutments and prosthetic parts and related surgical instruments.

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 and ISO 14801 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants. The worst case scenario for the Biodenta Dental Implant System - Bone Level implants and abutments was tested. These results show that Biodenta Dental Implant System - Bone Level have sufficient mechanical strength for their 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 - Bone Level is substantially equivalent to the predicate devices in intended use, material composition, fundamental scientific technology, principles of operation, and basic design. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Biodenta Dental Implant System - Bone Level.
### Substantial Equivalence Comparison to predicate device:

<table>
<thead>
<tr>
<th>Device</th>
<th>Biodenta Dental Implant System - Bone Level</th>
<th>Biodenta Dental Implant System (K093630)</th>
<th>Nobelactive Internal Connection Implant (K071370)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>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.</td>
<td>Biodenta 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.</td>
<td>Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.</td>
</tr>
<tr>
<td><strong>System</strong></td>
<td>threaded, root-form dental implant, bone level</td>
<td>threaded, root-form dental implant, tissue level</td>
<td>threaded, root-form dental implant, bone level</td>
</tr>
<tr>
<td><strong>Diameter</strong></td>
<td>3.5 mm, 4.1 mm, 4.8 mm</td>
<td>3.5 mm, 4.1 mm, 4.8 mm</td>
<td>3.5 mm, 4.3 mm, 5.0 mm</td>
</tr>
<tr>
<td><strong>Connection</strong></td>
<td>Internal Hexagon</td>
<td>Internal Octagon</td>
<td>Internal Hexagon</td>
</tr>
<tr>
<td><strong>Implant Material</strong></td>
<td>Titanium</td>
<td>Titanium</td>
<td>Titanium</td>
</tr>
<tr>
<td><strong>Abutment System</strong></td>
<td>Angled Abutment</td>
<td>Angled Abutment</td>
<td>Angled Abutment</td>
</tr>
<tr>
<td><strong>Abutment Angle</strong></td>
<td>0°, 15°</td>
<td>0°, 15°, 20°</td>
<td>0°, 15°</td>
</tr>
<tr>
<td><strong>Abutment Material</strong></td>
<td>Titanium Alloy</td>
<td>Titanium Alloy</td>
<td>Titanium Alloy</td>
</tr>
</tbody>
</table>
Mr. David Eiler  
Regulatory Manager  
Biodenta Swiss AG  
Tramstrasse 16  
9442 Berneck  
Switzerland

Re: K111003  
Trade/Device Name: Biodenta Dental Implant System – Bone Level  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: September 9, 2011  
Received: September 12, 2011

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 883); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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 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,

[Signature]

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

Enclosure
Indications for Use

510(k) Number (if known): \textbf{K111003}

Device Name: Biodenta Dental Implant System - Bone Level

Indications for Use:

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.

Prescription Use \textbf{X} \hspace{1cm} \textbf{AND/OR} \hspace{1cm} Over-The-Counter Use \\
(Part 21 CFR 801 Subpart D) \hspace{1cm} (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)

\begin{center}
\text{Susan} \hspace{1cm} \text{Sign-Off} \\
\text{Division of Anesthesiology, General Hospital} \\
\text{Infection Control, Dental Devices}
\end{center}

\textbf{510(k) Number: \textbf{K111003}}