K090069

1.4 510(k) Summary of Safety and Effectiveness

MAY - 7 2009

Submitted by:	Herbert Crane, Director Global Regulatory Affairs
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 5074
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Date of Submission:	January 9, 2009
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	Procera® Implant Bridge Overdenture
Legally Marketed Devices:	Nobel Biocare – Procera Implant Bridge (K041236) Nobel Biocare – Procera Implant Bridge (K043042) BIOMET 3i – CAM StructurSURE Precision Milled Bars

Device Description:
Nobel Biocare's Procera® Implant Bridge Overdenture is an overdenture bar that attaches to implants or abutments. The Procera® Implant Bridge Overdenture provides retention and support for a removable denture made of standard laboratory dental materials such as resin composite or porcelain veneer.

Procera® Implant Bridge Overdentures are made individually following instructions and models specific to each patient. The Procera® Implant Bridge is made entirely of titanium, titanium/vanadium alloy, or chromium/cobalt alloy.

The Procera® Implant Bridge Overdenture implant interfaces are the same as the predicate Procera Implant Bridges.

Indications for Use:
The Procera® Implant Bridge Overdenture is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Nobel Biocare AB
C/O Mr. Herbert Crane
Director, Global Regulatory Affairs
Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K090069
Trade/Device Name: Procera Implant Bridge Overdenture
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 1, 2009
Received: May 4, 2009

Dear Mr. Crane:

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Indications for Use

510(k) Number (if known): K090069

Device Name: Procera Implant Bridge Overdenture

Indications For Use:

The Procera Implant Bridge Overdenture is indicated for use as an overdenture bar that attaches to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mudry for MSR

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

510(k) Number: K090069