

JAN 27 2006

K053091

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Phuong Nguyen Son
Regulatory Affairs Specialist

Address: Nobel Biocare USA LLC
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

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Date of Submission: November 2, 2005

Classification Name: Endosseous Implant (21 CFR 872.3640)

Trade or Proprietary
or Model Name: Procera® Implant Bridge Zirconia

Legally Marketed Device(s): Procera® Implant Bridge (K043042)
Procera® Implant Bridge (K041236)

Device Description:

Procera® Implant Bridge Zirconia is a dental prosthetic framework milled from one solid piece of Zirconia (zirconium oxide). The many endosseous implant interfaces that can be used in the Procera® Implant Bridge Zirconia are precision milled and are an integral part of the framework.

The Procera® Implant Bridge Zirconia can be precision milled for two (2) to eight (8) units. The bridge is to function as a load-bearing device for implant-anchored prosthetics.

The Procera® Implant Bridge Zirconia is packaged as a semi-finished, non-sterile, device and delivered to the dental laboratory for veneering and completion. The final, veneered, Procera® Implant Bridge Zirconia is delivered from the dental laboratory to the clinician.

Indications for Use:

The Procera® Implant Bridge Zirconia is indicated for use as a bridge framework in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.

In addition to Nobel Biocare implant systems, the Procera® Implant Bridge Zirconia can be used on the following implant systems:

- Straumann Dental Implant System Regular Neck 4.8
- Straumann Dental Implant System Wide Neck 6.5
- 3i 3.75
- Lifecore Biomedical Restore 3.75
- Zimmer Dental Taper-Lock 4.0
- Sterngold Implamed 3.75



JAN 27 2006

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nobel Biocare AB
C/O Mr. Phuong Nguyen Son
Regulatory Affairs Specialist
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K053091
Trade/Device Name: Procera Implant Bridge Zirconia
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 22, 2005
Received: November 23, 2005

Dear Mr. Nguyen Son:

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.

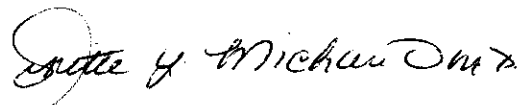
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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): K053091

Device Name: Procera Implant Bridge Zirconia

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- Sterngold Implamed 3.75

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Susan Runner

Director, Office of Device Evaluation
Center for Devices and Radiological Controls

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