

K043042

NOV 18 2004

1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Elizabeth J. Mason, Sr. Regulatory Affairs Specialist

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

Telephone: (714) 282-4800, ext. 7830

Facsimile: (714) 282-9023

Date of Submission: November 3, 2004

Classification Name: Endosseous Implant Abutment (21 CFR 872.3630)

Trade or Proprietary  
or Model Name: Procera® Implant Bridge

Legally Marketed Devices: Procera® Implant Bridge (K041236)  
3i Dental Abutment (K032263)  
Restore Self-Tapping Dental Implant System (K954512)  
Taper-lock Dental Implant System (K011038)  
Sterngold Implamed Hex Implant (K981516)

Device Description:

Nobel Biocare's Procera® Implant Bridge is a bridge framework that attaches to implants or abutments. The Procera® Implant Bridge framework is intended to be finished into a dental prosthesis using standard laboratory dental materials such as resin composite or porcelain veneer.

Procera® Implant Bridges are made individually following instructions and models specific to each patient. The Procera® Implant Bridge is made entirely of titanium.

The Procera® Implant Bridge implant interfaces are modeled after similar interfaces currently available for the predicate devices listed.

Indications for Use:

The Procera® Implant Bridge 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 the Brånemark implant, the bridge's hexagon connector interface fits the external hexagon of the following endosseous implants:

- 3i® 3.75
- Lifecore® Biomedical Restore 3.75
- Zimmer® Dental Taper-lock 4.0
- Sterngold Implamed® 3.75



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 18 2004

Nobel Biocare AB  
C/O Ms. Elizabeth J. Mason  
Senior Regulatory Affairs Specialist  
Nobel Biocare USA, LLC  
22715 Savi Ranch Parkway  
Yorba Linda, California 92887

Re: K043042  
Trade/Device Name: Procera<sup>®</sup> Implant Bridge  
Regulation Number: 872.3630  
Regulation Name: Endosseous Dental Implant Abutment  
Regulatory Class: II  
Product Code: NHA  
Dated: November 3, 2004  
Received: November 4, 2004

Dear Ms. Mason:

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" (21CFR 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/dsma/dsmamain.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): K043042

Device Name: Procera® Implant Bridge

Indications For Use:

The Procera® Implant Bridge 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 the Brånemark implant, the bridge's hexagon connector interface fits the external hexagon of the following endosseous implants:

- 3i® 3.75
- Lifecore® Biomedical Restore 3.75
- Zimmer® Dental Taper-lock 4.0
- 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)

*Ken Mulvey Sr. MSOE*

(Division Sign-Off)  
Division of Anesthesia, General Hospital,  
Infection Control, Dental Services

Page 1 of 1

510(k) Number:  K043042