

MAY 26 2004

K041236

1.4 510(k) Summary of Safety and Effectiveness

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

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Date of Submission: May 10, 2004

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Trade or Proprietary
or Model Name: Procera® Implant Bridge

Legally Marketed Devices: Nobel Biocare – Replace TiUnite Endosseous Implant (K023113)
Nobel Biocare – Branemark System Implants (K022562)
Steri-Oss – Steri-Oss Implants for Single Stage Placement (K963224)
Straumann – ITI synOcta Meso Abutments (K033243)

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 and abutment 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.

The Procera® Implant Bridge can be used at the implant or abutment level of the following implant systems:

- Nobel Biocare Brånemark System
- Nobel Biocare Replace Select

The Procera® Implant Bridge can be used at the implant level of the following implant systems:

- Nobel Biocare Replace
- Nobel Biocare Steri-Oss HL
- Nobel Biocare Novum
- Straumann Dental Implant System Regular neck 4.8
- Straumann Dental Implant System Wide neck 6.5

The Procera® Implant Bridge can be used at abutment level of the following implant systems:
Nobel Biocare ARK abutment for Teeth-in-Hour concept

1.5 Performance Standards

The Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Abutments; Draft Guidance for Industry and FDA was identified as applicable to this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2004

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

Re: K041236

Trade/Device Name: Procera Implant Bridge, Models 15-1001, 15-1002, 15-1051
Regulation Number: 372.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: NHA
Dated: May 10, 2004
Received: May 11, 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 (301) 594-4613. 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): K041236

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- Nobel Biocare ARK abutment for Teeth-in-Hour concept

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)

John P. ...

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

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