K042658

OCT 2 0 2004

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:	September 24, 2004
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	Procera® Abutment Brånemark
Legally Marketed Device(s):	Esthetic Zirconia Abutment (K031719) Procera® Abutment System (K974150) Ceramic Abutment (K913255) 3i Dental Abutment (K032263) Restore Self-Tapping Dental Implant System (K954512) Taperlock Dental Implant System (K011038) Sterngold ImplaMed Hex Implant (K981516)

Device Description:
The Procera® Abutment Brånemark is an artificial tooth abutment designed to fit and function on root-form endosseous implants having an external hexagon abutment interface.

Nobel Biocare's Procera® Abutment Brånemark is intended for use in the treatment of partially edentulous patients in order to restore chewing function. The Procera® Abutment Brånemark is a prosthetic device that fits Nobel Biocare's Brånemark external hexagon endosseous implant as well as the endosseous implants specifically indicated. The device has been developed for long-term, permanent use.

Nobel Biocare's Procera® Abutment Brånemark can be made from titanium, alumina, or zirconia.

Indications for Use:
Nobel Biocare's Procera® Abutment Brånemark is indicated for the treatment of partially edentulous patients requiring a prosthetic device. In addition to the Brånemark implant, the abutment's hexagon connector fits the external hexagon of the following endosseous implants:

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

1.5 Performance Standards

The Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments; Guidance for Industry and FDA Staff (May 12, 2004) was identified as applicable to this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

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

Re: K042658
Trade/Device Name: Procera® Abutment Brånemark
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 24, 2004
Received: October 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):

Device Name: Procera® Abutment Brånemark

Indications For Use:

Nobel Biocare's Procera® Abutment Brånemark is indicated for the treatment of partially edentulous patients requiring a prosthetic device. In addition to the Brånemark implant, the abutment's hexagon connector fits the external hexagon of the following endosseous implants:

- 3i® 3.75
- Lifecore® Biomedical Restore 3.75
- Zimmer® Dental Taperlock 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)

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

510(k) Number: K042658