

K062566

1.4 510(k) Summary of Safety and Effectiveness

DEC - 6 2006

Submitted by: Ms. Phuong Nguyen Son
Regulatory Affairs Specialist

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Date of Submission: August 30, 2006

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Trade or Proprietary
or Model Name: NobelReplace Tapered Conical Connection

Legally Marketed Device(s): Groovy Implants (K050258)
SFB & CFB Implants (K061003)

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Device Description:

Nobel Biocare's NobelReplace Tapered Conical Connection implants are threaded, root-form dental implants intended for use in the upper and lower jaw arches to support prosthetic devices, such as an artificial tooth, in order to restore esthetics and chewing function to partially or fully edentulous patients.

The NobelReplace Tapered Conical Connection implants are similar in design to the NobelReplace Tapered implants cleared under "Groovy Implants" (K050258). Like the NobelReplace Tapered implant, the NobelReplace Tapered Conical Connection implant is machined from commercially pure titanium, grade 4, have a tapered body contour, grooves on the collar, grooves on the threads of the body, and a TiUnite[®] surface treatment. The difference between the two implants is that the NobelReplace Tapered Conical Connection implants have the same internal conical connection as the SFB implants, cleared under "SFB & CFB Implants"(K061003). The internal conical connection allows for the use of SFB abutments.

Indications for Use:

Nobel Biocare's NobelReplace Tapered Conical Connection implants are endosseous dental implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. The NobelReplace Tapered Conical Connection implants are indicated for single or multiple unit restorations. The NobelReplace Tapered Conical Connection implants can be used in splinted or non-splinted applications. The NobelReplace Tapered Conical Connection implant may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2006

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

Re: K062566

Trade/Device Name: NobelReplace Tapered Conical Connection
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: November 22, 2006
Received: November 24, 2006

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.

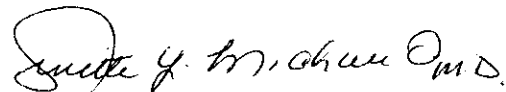
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

K062566

1.3

Indications for Use

510(k) Number (if known): K062566

Device Name: NobelReplace Tapered Conical Connection

Indications For Use:

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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)



Department of Otolaryngology, General Hospital
FDA, Center for Device Evaluation and Research, Dental Devices

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