

K081128

#### 1.4 510(k) Summary of Safety and Effectiveness

Submitted by: Herbert Crane  
Director, Global Regulatory Affairs

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

Telephone: (714) 282-4800, ext. 5074

Facsimile: (714) 282-9023

Date of Submission: April 18, 2008

Classification Name: Endosseous Dental Implant (21 CFR 872.3640)

Trade or Proprietary  
or Model Name: Molar Implant

Legally Marketed Device(s): TiUnite Implants (K050705)  
NobelSpeedy Implants (K050406)  
Groovy Implants (K050258)  
NobelActive Internal Connection Implant (K071370)

Device Description:

Nobel Biocare's Molar 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 Molar Implants are similar in design to the NobelSpeedy, Groovy, TiUnite, and NobelActive Internal Connection Implants. Like these implants, the Molar Implants are manufactured from commercially pure titanium. The implants utilize the TiUnite surface treatment and have the Groovy groove design feature.

Indications for Use:

Nobel Biocare's Molar 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 Molar Implants are indicated for single or multiple unit restorations in the molar region. The Molar Implants can be used in splinted or non-splinted applications. The Molar Implants 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

NOV - 7 2008

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

Re: K081128  
Trade/Device Name: Molar Implant  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: October 3, 2008  
Received: October 6, 2008

Dear Ms. Nguyen:

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.

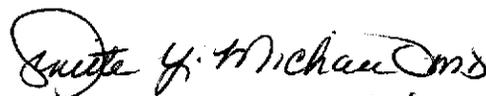
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

  
FOR DR. CHIU LIN

Chiu S. Lin, Ph. D  
Division 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): K081128

Device Name: Molar Implant

Indications For Use:

Nobel Biocare's Molar 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 Molar Implants are indicated for single or multiple unit restorations in the molar region. The Molar Implants can be used in splinted or non-splinted applications. The Molar Implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.

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)

*MSR*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K081128