K050705

1.4 510(k) Summary of Safety and Effectiveness

MAY 19 2005

Submitted by:	Herbert Crane Manager, Regulatory Affairs
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 5074
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Date of Submission:	March 18, 2005
Classification Name:	Endosseous Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	TiUnite™ Implants
Legally Marketed Device(s):	Nobel Biocare Endosseous Implants (K041661)

Device Description:
Nobel Biocare TiUnite™ Implants are threaded, root-form dental implants intended for use in the upper and/or lower jaw to support prosthetic devices, such as artificial teeth, in order to restore patient esthetics and chewing function to partially or fully edentulous patients.

TiUnite™ Implants machined from titanium and have a surface treatment consisting of a thin, uniform titanium oxide (TiUnite™) layer. Nobel Biocare TiUnite™ Implants are available with a straight or tapered contour.

Nobel Biocare TiUnite™ Implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be immediately loaded following insertion where good initial stability can be obtained.

Due to a more rapid formation and greater amount of bone to implant contact during healing, Nobel Biocare's TiUnite® surfaced implants result in faster and stronger osseointegration and better maintenance of the initial implant stability than machined titanium implants. When placed in soft bone and immediately loaded, the faster and stronger osseointegration of Nobel Biocare's TiUnite® surfaced implant results in a higher success rate compared to machined implants.

Indications for Use:
Nobel Biocare TiUnite® Implants are root-form endosseous 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. Nobel Biocare TiUnite® Implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare TiUnite® Implants may be placed immediately and put into immediate function providing that the initial stability requirements detailed in the surgical manuals are satisfied.

TiUnite™ implants are indicated for use in soft bone whenever immediate or early loading is applied. The TiUnite™ implants are preferred in these soft bone indications because bone formation is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

Nobel Biocare AB
C/O Mr. Herbert Crane
Manager Regulatory Affairs
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K050705
Trade/Device Name: TiUnite® Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: March 17, 2005
Received: March 18, 2005

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.

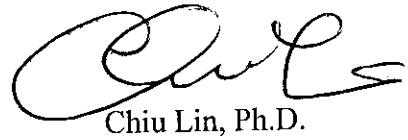
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 443-6597 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

1.3

Indications for Use

510(k) Number (if known): K050705

Device Name: TiUnite® Implants

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Susan Runner

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

510(k) Number K050705