AUG 2 0 2004

K041876

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason Sr. Regulatory Affairs Specialist
Address:	Nobel Biocare USA Inc. 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 7830
Facsimile:	(714) 998-9348
Date of Submission:	July 9, 2004
Classification Name:	Endosseous Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	NobelDirect™ OD Implant
Legally Marketed Device(s):	Brånemark System Implants (K022562) Replace One-Piece Implants (K023952)

Device Description:
Nobel Biocare's NobelDirect™ OD Implant is a threaded one-piece root form endosseous implant with an integrated ball attachment designed for one-stage surgical procedures and overdenture restorations. The NobelDirect™ OD Implant is intended to provide immediate retention for removable tissue supported lower overdentures in fully edentulous jaws.

Nobel Biocare's NobelDirect™ OD Implant can be placed in an edentulous arch or placed simultaneously with tooth extraction. When using the Nobel Biocare's NobelDirect™ OD Implant in immediate function applications, it is essential to obtain primary implant stability. Nobel Biocare's Gold Cap for Ball Attachment is to be utilized with the NobelDirect™ OD Implant.

Nobel Biocare's NobelDirect™ OD Implant is machined from titanium and is available with a straight or tapered contour. The NobelDirect™ OD Implant has a surface treatment that consists of a titanium oxide layer (TiUnite) that extends over the implant threads and onto the implant collar.

Indications for Use:
The NobelDirect™ OD Implant is a root form endosseous implant intended to provide immediate retention for removable tissue supported lower dentures in fully edentulous patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2004

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

Re: K041876
Trade/Device Name: NobelDirect™ OD Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: July 9, 2004
Received: July 21, 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.

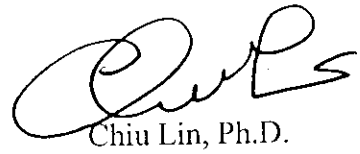
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K041876

Device Name: NobelDirect™ OD Implant

Indications For Use:

The NobelDirect™ OD Implant is a root form endosseous implant intended to provide immediate retention for a removable tissue-supported overdenture. The NobelDirect™ OD Implant is used in the intra-foraminal area of the anterior mandible for the fully edentulous lower arch.

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)

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

510(k) Number: K041876