K031345

JUL 24 2003

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:	April 28, 2003
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Nobel Direct
Legally Marketed Device:	Replace® One Piece Implant (K023952) (also known as > Nobel Direct)

Device Description:

Nobel Biocare's **Nobel Direct** is a name change of the legally marketed device "Replace® One Piece Implant" (K023952).

Nobel Biocare's **Nobel Direct** utilizes the same material and fundamental design as the unmodified, predicate device, "Replace® One Piece Implant" (K023952).

Nobel Biocare's **Nobel Direct** incorporates a design modification by adding an endosseous implant with a diameter of 3.0mm to the existing diameter sizes already in the Nobel Direct product line.

The Nobel Direct 3.0mm implant is restricted for use only in the maxillary lateral position or the mandibular central and lateral incisor position. The Nobel Direct 3.0mm implant/abutment is only available in lengths of 13mm and 15mm. The lengths of the implant represent the portion of the unit placed in the bone *(i.e. threaded portion)*.

Indications for Use:

The Nobel Direct 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

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

Re: K031345
Trade/Device Name: Nobel Direct
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: DZE
Product Code: III
Dated: April 28, 2003
Received: April 29, 2003

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.

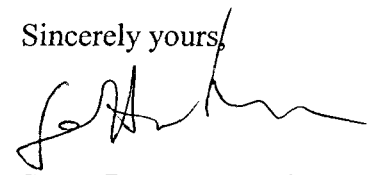
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



for Susan Runner, DDDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.3 Statement of Indications for Use

510(k) number *(if known)*: K031345

Device Name: Nobel Direct

Indications for Use:
The Nobel Direct 3.0mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients.

Mandible central and lateral incisors must be splinted if using two or more 3.0mm implants adjacent to one another.

(Please do not write below this line – Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R&Betz DDS for Dr. K. Mulry
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K031345

(Optional Format 3-10-98)