K050393

MAY - 4 2005

1.4 510(k) Summary of Safety and Effectiveness

Submitted by:	Elizabeth J. Mason Sr. Regulatory Affairs Specialist
Address:	Nobel Biocare USA LLC 22715 Savi Ranch Parkway Yorba Linda, CA 92887
Telephone:	(714) 282-4800, ext. 7830
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Date of Submission:	February 16, 2005
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	The Guided Surgery Concept
Legally Marketed Device(s):	Teeth in an Hour – ARK Implant Concept (K030685)

Device Description:
The Guided Surgery Concept is intended for the treatment of totally and partially edentulous jaws as well as single unit cases. The Guided Surgery Concept enables a predictable, fast and minimally invasive endosseous dental implant installation procedure according to case planning done by the clinician.

The Guided Surgery Concept enables the final prosthesis to be produced prior to and attached in the same session as the implant installation. The entire procedure is typically completed within one hour and can be used for the treatment of totally and partial edentulous patients as well as patients missing a single tooth.

The Guided Surgery Concept includes 3D Planning Software that enables the clinician to view three-dimensional CT-scan data as well as to plan the case in a virtual three-dimensional environment. This case planning can be used to produce a Surgical Template, thus transferring the virtual case planning into physical tools enabling the surgical installation according to the virtual case planning.

The Guided Surgery Concept is based upon knowledge of the location and orientation of the implant(s) prior to the surgery. This knowledge enables the production of a Surgical Template. Aided by the Surgical Template, the sites can be prepared and the implants placed in the predetermined locations enabling the immediate attachment of the prefabricated temporary or final prosthesis.

Indications for Use:
The Guided Surgery Concept and Teeth-in-an-Hour are indicated for the treatment of single, partially and totally edentulous jaws for placement of implant fixtures with immediate function to restore patient esthetics and chewing function. The following prerequisites must be fulfilled:
– adequate amount of jaw bone
– the quality of jaw bone must be judged as adequate

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K050393
Trade/Device Name: The Guided Surgery Concept
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: February 16, 2005
Received: February 16, 2005

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.

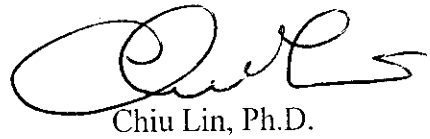
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K050393

Device Name: The Guided Surgery Concept

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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)

Kai Mulay for MSK

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

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