FEB - 1 2005 K043312

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
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Date of Submission:	November 30, 2004
Classification Name:	Porcelain Powder for Clinical Use (21 CFR 872.6660)
Trade or Proprietary or Model Name:	NobelRondo Dental Ceramic – Zirconia
Legally Marketed Device(s):	NobelRondo Dental Ceramic – Alumina (K041312)

Device Description:
NobelRondo Dental Ceramic – Zirconia is dental porcelain intended for use in the construction of zirconium oxide ceramic prosthetics. NobelRondo consists of sixteen (16) porcelain shades corresponding to Vita shades A0-C3 and various shade modifiers. The shade modifiers are intended to give the user flexibility in creating a translucent or opalescent natural looking prosthetic. NobelRondo also includes mixing liquids and shade guides.

The various porcelains and modifiers are used in a build-up process. After applying each layer, the restoration is fired following directions in the Instructions for Use. All of the component porcelains and modifiers can be used in combination without restriction. The dental technician will use the components as needed to create the desired prosthetic. However, typical use includes using a base liner followed by a build-up material and finally glazes and stains. Throughout this process, modifiers for translucent and opalescent effects can be added.

The NobelRondo Dental Ceramic – Zirconia is sold in kit form. The various porcelains and modifiers are packaged in polyethylene bottles with screw caps. Replacement bottles for each porcelain or modifier are available individually.

Indications for Use:
NobelRondo Dental Ceramic – Zirconia is a ceramic material intended for veneering substructures such as single crowns, multiple frameworks or abutments made from zirconia.

1.5 Performance Standards

NobelRondo Dental Ceramic – Zirconia conforms with the following standards:

ISO 6872:1995 – Dental Ceramic
ISO 7405:1997 – Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry – Test Methods for Dental Materials
ISO 9693:1999 – Metal-ceramic Dental Restorative Systems

These standards correspond to recognized consensus standards established under section 514 of the Federal Food, Drug, and Cosmetic Act for dental porcelain powder.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

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

Re: K043312
Trade/Device Name: NobelRondo Dental Ceramic - Zirconia
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: November 30, 2004
Received: December 1, 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.

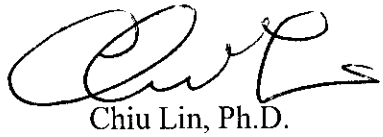
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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): K043312

Device Name: NobelRondo Dental Ceramic - Zirconia

Indications For Use:

NobelRondo Dental Ceramic Zirconia is a ceramic material intended for veneering substructures such as single crowns, multiple frameworks or abutments made from zirconia.

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 Runyon

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

510(k) Number: K043312