K050444

JUL 7 - 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
Facsimile:	(714) 282-9023
Date of Submission:	February 18, 2005
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Trade or Proprietary or Model Name:	NOBELREPLACE® Adapter
Legally Marketed Device(s):	Replace Scalloped Margin Implant System (K021584) Nobel Biocare Permanent Centric Post (K040573)

Device Description:
Nobel Biocare's NOBELREPLACE® Adapter is a hollow titanium alloy device intended for use as an accessory component designed to adapt a smaller platform abutment to a larger platform endosseous implant to a within the implant/abutment system.

The NOBELREPLACE® Adapter provides a gradual transition from abutment to implant, and can only be used as part of the implant/abutment system, not on its own. It is designed to remain a component of the implant/abutment system for as long as the implant remains in the patient's mouth.

Indications for Use:
Nobel Biocare's NOBELREPLACE® Adapter is a bushing that enables seating of a smaller diameter abutment to a larger diameter endosseous implant in an implant-supported dental restoration of a partially or fully edentulous jaw in order to restore patient esthetics and chewing function.

2.4 Legally Marketed Device Information

The legally marketed equivalent devices are listed below:

Predicate Device:	Replace Scalloped Margin Implant System
Predicate 510(k):	K021584
Company:	Nobel Biocare
Predicate Device:	Nobel Biocare Permanent Centric Post
Predicate 510(k):	K040573
Company:	Nobel Biocare

A comparison of the attributes and intended use of the candidate device, NOBELREPLACE® Adapter, with those of the predicate device is provided in Section 2.5.

Section 2.5 Substantial Equivalence Comparison to Predicate Devices

ATTRIBUTE	CANDIDATE	PREDICATE	PREDICATE
	NOBELREPLACE® Adapter	*Replace Scalloped Margin Implant System (K021584)*	*Nobel Biocare Permanent Centric Post (K040573)*
Anatomical Site	• **Oral Cavity**	• *Oral Cavity*	• *Oral Cavity*
Abutment Diameter	• **5.0 mm**	• *3.5mm* • *4.3mm* • *5.0mm*	• *3.5mm* • *4.3mm* • *5.0mm*
Implant-Supported Device	• **Yes**	• *Yes*	• *Yes*
Raw Material	• **Titanium Vanadium Alloy**	• *Titanium Vanadium Alloy (abutments)*	• *Santoprene*
Intended Use	• **Permanent**	• *Permanent*	• *Permanent*
Load-Bearing Member of Implant/Abutment System	• **Yes**	• *Yes*	• *No*
Sterility	• **Sterile**	• *Sterile (endosseous implants)*	• *Non-Sterile*
Indications for Use	**Nobel Biocare's NOBELREPLACE® Adapter is a bushing that enables seating of a smaller diameter abutment to a larger diameter endosseous implant in an implant-supported dental restoration of a partially or fully edentulous jaw in order to restore patient esthetics and chewing function.**	*The Replace Scalloped Margin Implant System is an implant with a scalloped coronal margin, designed for single stage or two stage surgical procedures. The Replace Scalloped Margin Implant System is intended for use to restore chewing function in edentulous and/or partially edentulous patients.*	*The Nobel Biocare Permanent Centric Post is a support component indicated for use as both an alignment post to center an abutment, and as a seal to prohibit fluids from seeping into the implant interior. The Nobel Biocare Permanent Centric Post is a component within the implant system, and is intended for use in permanent restorations in order to restore the chewing function of fully edentulous and/or partially edentulous patients.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 - 2005

Mr. Herbert Crane
Director of Regulatory Affairs
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K050444
Trade/Device Name: NOBELREPLACE® Adapter
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: June 9, 2005
Received: June 10, 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.

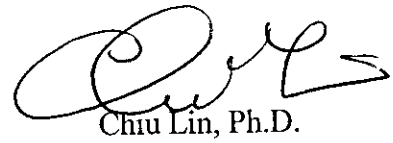
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K050444

Device Name: NOBELREPLACE® Adapter

Indications For Use:

Nobel Biocare's NOBELREPLACE® Adapter is a bushing that enables seating of a smaller diameter abutment to a larger diameter endosseous implant in an implant-supported dental restoration of a partially or fully edentulous jaw in order to restore patient esthetics and chewing function.

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)

Kevin Mulley for WSR

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

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