MAY 2 9 2002

K020646

Nobel Biocare

510(k) Summary

Establishment Information	Nobel Biocare USA, Inc. 22715 Savi Ranch Parkway Yorba Linda, CA 92887 USA Phone: 1-800-993-8100, ext 5074 Fax: 1-714-998-9348
Contact	Vincent Cheung Manager, Regulatory Affairs & Quality Assurance (714) 282-5074
Proprietary device name	Replace™ HA Coated Implant (K962845) Steri-Oss 3.25 mm Replace™ HA Coated Implant (K973423)
Classification name	Endosseous Dental Implant (21 CFR 872.3640)
Device classification	Class III
Statement	The information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below.
Device description	The Replace ™ HA Coated Implant is to serve as a support for prosthetic devices to restore a patient's chewing function. The available diameters are 3.5 mm, 4.3 mm, 5.0 mm and 6.0 mm with lengths of 10 mm, 13 mm, and 16 mm. The titanium alloy implant has an HA coating on the root form portion to within approximately 2 mm of the top.
Intended use	The intended use of the Replace HA Coated Implants is for restoring chewing function by serving as anchorage for dental restorations.

Nobel Biocare USA, Inc. 22715 Savi Ranch Parkway, Yorba Linda, CA 92887
Telephone (714) 282-4800 (800) 993-8100
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Indications for use	The Replace HA Coated Implant is both for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Replace HA Coated Implant is intended for immediate placement and function on single tooth and/or multiple tooth applications in good quality bone (type I or type II bone), to restore chewing function.
Technological characteristics	The technological characteristics of the Replace HA Coated Implants remained unchanged. No design modification was made.
Performance data	Clinical results show that the expanded Indications for Use is as safe and effective as the original Indications for Use.
Conclusion	Based on the 510(k) summaries, 510(k) statements and the information provided herein, we conclude that the expanded Indications for Use is substantially equivalent to the currently marketed device under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 9 2002

Mr. Vincent Cheung
Manager, Regulatory Affairs & Quality Assurance
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K020646
Trade/Device Name: Replace HA Coated Implant Models, 35102, 35132, 35162, 43132, 43162
Regulation Number: 876.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: February 26, 2002
Received: February 28, 2002

Dear Mr. Cheung:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K020646
Device Name: Replace™ HA Coated Implant

Indications for Use:

The Replace™ HA Coated Implant is for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Replace HA Coated Implant is intended for immediate placement and function on single tooth and/or multiple tooth applications in good quality bone (type I or type II bone), to restore chewing function.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (per 21 CFR 801.109) OR Over-the-Counter Use _____
Optional Format 1-2-96

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020646