K023952

5. 510(K) SUMMARY

JAN 16 2003

Establishment Nobel Biocare USA, Inc.
22715 Savi Ranch Parkway
Yorba Linda, CA 92887

Phone: 800 993-8100
Fax: 714 998-9348

Contact Kathleen Dragovich
Regulatory Affairs Specialist
(714) 282-4800, ext. 7834

Proprietary Device Name Replace® One Piece Implant

Classification Name Endosseous Dental Implant (21 CFR 872.3640)

Device Classification Class III

Device Description

The Replace® One Piece Implant is a one-piece, threaded root-form implant based on the Nobel Biocare Replace® implant design. The new configuration of the implant is designed with an integrated abutment that will eliminate the step of attaching the abutment.

This combination of design characteristics also includes acid etching of the transmucosal/transgingival neck to encourage connective tissue attachment for esthetics purposes. The device is manufactured of CP4 Titanium and is offered in TiUnite™ and HA Coating. This device will be offered in diameters of 3.5, 4.3, and 5.0mm, each in lengths of 10, 13, and 16mm.

This implant is designed for immediate load applications in partially edentulous patients.

Indications for Use

The Replace® One Piece Implant is a threaded one-piece implant with an integrated abutment, designed for single-stage surgical procedure and cemented restorations. The Replace® One Piece Implant is intended for immediate load on single tooth and multiple tooth applications in good quality bone, to restore chewing function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kathleen Dragovich
Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

JAN 16 2003

Re: K023952
Trade/Device Name: Replace® One Piece Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: November 26, 2002
Received: November 27, 2002

Dear Ms. Dragovich:

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. 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) you may obtain. 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8. INDICATIONS FOR USE STATEMENT

K023952

510(k) Number (if known): Not yet assigned

Device Name: Replace® One Piece Implant

Indications for Use:

The Replace® One Piece Implant is a threaded one-piece implant with an integrated abutment, designed for single-stage surgical procedure and cemented restorations. The Replace One Piece Implant is intended for immediate load on single tooth and multiple tooth applications in good quality bone, to restore chewing function.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

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

Susan Runyon

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

510(k) Number K023952