K021584

JUN 0 5 2002

Nobel Biocare

Section 1.5

Safety and Effectiveness Summary

Submitted by:	Richard T. Ross, RAC Senior Regulatory Affairs Specialist	
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Date Submitted:	April 26, 2002	
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)	
Trade or Proprietary or Model Name:	Replace™ Scalloped Margin Implant System	
Legally Marketed Device:	Replace™ HA Coated Implant	K962845

Device Description:

The Replace™ Scalloped Margin Implant System is an implant with a scalloped coronal margin designed to mimic the contours of the alveolar ridge. The implant is designed for esthetic applications where the alveolar ridge and the soft tissues are relatively intact.

The available diameters will be 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 implant body will be available with an HA coating on the root form portion.

Indications for Use:

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 2 2002

Mr. Richard T. Ross
Senior Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K021584
Trade/Device Name: Replace Scalloped Margin Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: III
Product Code: DZE
Dated: May 13, 2002
Received: May 14, 2002

Dear Mr. Ross:

This letter corrects our substantially equivalent letter of June 5, 2002 regarding the trade name.

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). 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 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

Section 1.4

Indications for Use Statement

K021584

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

Device Name: Replace™ Scalloped Margin Implant System

Indications for Use:

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.

(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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021584