K030257

510(k) Summary of Safety and Effectiveness

FEB 1 0 2003

Submitted by:	Elizabeth J. Mason, Sr. Regulatory Affairs Specialist
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Date of Submission:	January 22, 2003
Classification Name:	Endosseous Dental Implant (21 CFR 872.3640)
Trade or Proprietary or Model Name:	Nobel Perfect Implant System
Legally Marketed Device:	Replace Scalloped Margin Implant System (K021584)

Device Description:
The Nobel Perfect Implant System is a name change of the legally marketed device Replace Scalloped Margin Implant System. The Nobel Perfect Implant System utilizes the same components *(i.e. implant, abutment, etc.)* as the predicate device, Replace Scalloped Margin Implant System (K021584), yet contains three design modifications.

First, the screw-retained healing cap is now designed as a shorter, cover plug. The design modification was developed in order to attain a better seal and reduce the overall height of the implant by lowering its profile.

Second, a silicone o-ring has been added to the implant system. The o-ring is intended to be placed between the implant and the healing abutment in order to prevent fluids and tissue from seeping between the two parts during the healing process.

Third, changes in materials have been specified. The material used to manufacture the former screw-retained healing cap was acetal (Delrin). The cover plug and the o-ring will be made from a medical grade translucent silicone. The material used for the manufacture of the healing abutment has changed from acetal (Delrin) to polysulfone so that it may be radiation sterilized.

Indications for Use:
The indications for use for the Nobel Perfect Implant System are the same as the unmodified device, Replace Scalloped Margin Implant System. It is a system with a scalloped coronal implant designed for single stage or two stage surgical procedures. The Nobel Perfect 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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 14, 2012

Ms. Elizabeth J. Mason
Senior Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
YORBA LINDA CA 92887

Re: K030257
Trade/Device Name: Nobel Perfect Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 22, 2003
Received: January 24, 2003

Dear Ms. Mason:

This letter corrects our substantially equivalent letter of February 10, 2003 regarding the product code and regulatory class.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner DDS, MA 2012.12.14 10:49:43 -05'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) number *(if known)*: K030257

Device Name: Nobel Perfect Implant System

Indications for Use:
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(Please do not write below this line – Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

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

510(k) Number: K030257