K961728

JUL 10 1996

VI. 510(k) Summary of Safety and Effectiveness

A. Name and Address

This Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. Their telephone number is (708) 654-9100. The contact person will be the Director, Regulatory Affairs. This summary was prepared on May 1, 1996.

B. Name of the Device

This device is known as an abutment to an endosseous implant with the trade name BRÅNEMARK SYSTEM® MirusCone Abutment System. This submission is a modification to a previously cleared device, K944964.

C. The Predicate Product

The predicate product used in this Premarket Notification is the previous version of the same device, MirusCone Abutment System, K944964.

D. Description of the Device

The Nobelpharma MirusCone Abutment System is an abutment used with an endosseous implant which is implanted in the upper or lower jaw bone. The abutment has a lower profile (vertical height) for use when the dentist desires a lower profile abutment. The only modifications to the device are the broadening and narrowing of the base and external diameters of the abutments; and broadening and narrowing of the diameters of the abutment screws, adding two series of abutments fitting the larger and smaller diameters of fixture previously cleared.

E. Intended Use of the Device

The Nobelpharma MirusCone Abutment System is intended to be used in edentulous patients as an anchor to support a prosthesis.

F. Comparison of Technological Characteristics

The technological characteristics between the modified version of the MirusCone Abutment and the earlier version are identical. The only changes are minor dimensional changes to the diameters of the abutment, the abutment screw and the prosthetic screw.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2010

Ms. Phuong Nguyen Son
Regulatory Affairs Manager
Nobel Biocare USA, LLC
22715 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K961728
Trade/Device Name: MirusCone Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 28, 2010
Received: July 29, 2010

Dear Ms. Nguyen Son:

This letter corrects our substantially equivalent letter of July 28, 2010.

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 (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.

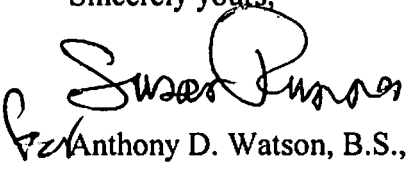
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

)(k) Number (if known): K961728

Device Name: MirusCone Abutment System

Indications For Use:

Intended to be used in edentulous patients as an anchor to support a prosthesis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Susan Runyon
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K961728

ption Use ✓ OR Over-The-Counter Use
er 21 CFR 801.109)

(Optional Format 1-2-96)

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