K972475

SEP 12 1997

VII. 510(k) Summary of Safety and Effectiveness

A. Name and Address

This Summary of Safety and Effectiveness is being submitted by Nobel Biocare USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. The telephone number is: (630) 654-9100, extension 2002, and the contact person will be Betsy Brown, the Vice President, Regulatory Affairs.

B. Name of the Device

This device system consists of various modifiable gold alloy abutments, abutment screws, a counter torque device with handle, adaptors, machine Uni-grip screwdrivers with autoclavable box, temporary cylinders, temporary tubes, laboratory screws and impression copings.

C. The Predicate Product

The predicate products used in this Pre-market Notification are similar components marketed by Nobel Biocare including the UCLA - Type Abutments (K934495), CeraOne™ Abutment Screw (K961737), Guide Pin (K911969), Abutment Lab-Screw (K925769), CerAdapt™, Machine Counter Torque Device (K953775), EsthetiCone Temporary Cylinder (K925766), Miruscone Temporary Cylinder (K962403), Temporary Tube (K926766), Titanium Impression Coping (K952448), Plastic Impression Coping (K910611), CeraOne™ Screwdrivers (K922805) and Fixture Guide Set Tray (K944963).

D. Description of Device

The Nobel Biocare AurAdapt™ Abutment System is a set of modifiable gold alloy abutments which are secured directly to the dental fixtures using a gold abutment screw. These abutments (also referred to as "Gold Cylinder to Fixture" abutments) can be casted into a screw retained dental prosthesis or reshaped by wax-up techniques to anchor a cemented prosthesis. When more than one of the modifiable abutments are used, a multi-unit bridge can be attached to the abutments.

E. Intended Use of the Device

Nobel Biocare's **AurAdapt™ Abutment System** is a set of screw retained modifiable gold alloy abutments that are secured to an endosseous implant and are intended to function as an anchor to which prosthetic devices, such as artificial teeth, may be attached by a screw or by dental cement to restore a patient's chewing function.

F. Comparison of Technological Characteristics

The technological characteristics between the components of the **AurAdapt Abutment System** and the corresponding predicate products found in the Brånemark System® are identical.

Summary Of Safety And Effectiveness Concerns

Safety and effectiveness problems that have been encountered with similar Abutment Systems used with endosseous implants that are currently being marketed include:

1. occasional fractures of the screw attaching the abutment to the fixtures usually due to functional overload from masticastory forces;

2. screws working loose (usually because torque force below recommended values was applied when the abutment was attached to the fixture) may lead to the formation of granulation tissue at the level of the fixture and abutment connection which may, in turn, result in infection;

3. improper initial seating of abutments resulting in gingival inflammation and fistulae formation, both conditions resolve when proper seating of the abutment is accomplished.

4. occasional fracture of the abutment screw which is usually caused by poorly designed and/or fabricated restorations that creates overloads or cause's metal fatigue.

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

Re: K972475
Trade/Device Name: Auradapt 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.

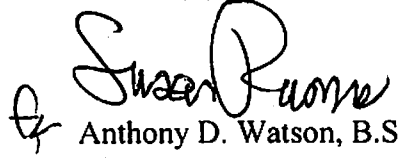
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

510(k) Number (if known): K972475

Device Name: AurAdapt™ Abutment System

Indications For Use:

Nobel Biocare's AurAdapt Abutment System is a set of screw retained modifiable gold alloy abutments which are secured to an endosseous implant and is intended to function as an anchor to which prosthetic devices, such as artificial teeth, may be attached using dental cement to restore a patient's chewing function.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K972475

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)