IV. Special Controls

To date, no Section 514 performance standard or their special controls have been established for gold cylinder and screw components of endosseus implants.

V. Proposed Labeling

Proposed labeling for the Brånemark System® Gold Cylinders and Screws is attached as Exhibit A.

VI. Certification

I certify that a reasonable search of information known or otherwise available to Nobelpharma regarding the types and causes of reported safety and effectiveness problems for the components of an endosseous implant system has been conducted. I further certify that the types of problems to which the endosseous implant is susceptible and their potential causes are listed in the Class III summary, below, and that the class III summary is complete and accurate. The following provides the basis for this certification.

VII. Class III Summary of Safety and Effectiveness

Safety and effectiveness problems which have been experienced with similar components used with currently marketed endosseous implant systems include:

1. gingivitis and gingival hyperplasia, often due to poor oral hygiene or improper height selection of the cylinder;

2. screw fracture due to overtightening or improper prosthetic design and subsequent mechanical overload;

3. improper initial seating of cylinder resulting in gingival inflamation and fistulae formation, both conditions resolve when proper seating is accomplished.

Nobelpharma bases these descriptions on the following sources of information:

- Nobelpharma manufactures the Branemark System® of endosseous implants. Professor Per-Ingvar Branemark, who developed this technology is a pioneer of osseointegrated implant biotechnology and has written numerous scientific articles and books on this subject. Nobelpharma is familiar with Professor Branemark's publications relevant to the fixture components for endosseous implant systems.

- Nobelpharma's knowledge of possible complications with endosseous implants and their components has been gleaned from their own extensive experience in the industry.

- Nobelpharma remains current with novel developments in the biotechnology. Nobelpharma's personnel review current literature and attend numerous meetings and symposia which cover various aspects of endosseous implant biotechnology.

- In addition to the above, the stated potential safety and effectiveness problems were gleaned from the following publications:

Worthington, Bolender, and Taylor, "The Swedish System of Osseointegrated Implants: Problems and Complications Encountered During a 4-Year Trial Period," Int. J. Oral Maxillofac. Impl., 1987;2, 77-84.

Branemark, Hansson, Adell, Breine, Lindstrom, Hallen, Ohman, Osseointegrated Implants in the Treatment of Edentulous Jaw: Experience from a 10-Year Period, (1977).

Adell, R., et al., "Marginal Tissue Reactions at Osseointegrated Titanium Fixtures. A Three-year Longitudinal Prospective Study," Int. J. Oral Maxillofac. Surgery, 1986;15;53-61.

Laney, W., et al., "Dental Implants: Tissue Integrated Prosthesis Utilizing the Osseointegrated Concept," Mayo Clinic Proceedings, 1986, Vol. 61, 91-97.

Zarb G.A., Schmitt, A., "The Longitudinal Clinical Effectiveness of Osseointegrated Dental Implants: The Toronto Study." J. Pros. Dent., 1990, 64: 185-194.

These publications, in turn, cite hundreds of scientific articles authored by Branemark and others which cover various aspects of endosseous implant biotechnology. A copy of the articles are attached as Exhibit B.

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: K925769
Trade/Device Name: Branemark System Abutments Complete
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.

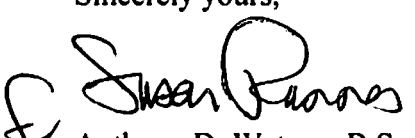
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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