K022562

OCT 11 2002

Section 1.7

510(k) Summary

Establishment Information	Nobel Biocare AB 15 Bohusgatan P.O. Box 5190 Goteborg, Sweden S-402 26 Phone: 1-800-993-8100, ext 5073 Fax: 1-714-998-9348
Contact	Kathleen Dragovich Regulatory Affairs Specialist (714) 282-4800, ext. 7834
Proprietary Device Name	Various Brånemark System Dental Implant Products
Classification Name	Endosseous Dental Implant (21 CFR 872.3640)
Device Classification	Class III
Statement	The information supporting claims of substantial equivalence, as defined under the Federal Food, Drug, and Cosmetic Act, respecting safety and effectiveness is summarized below.
Device Description	The Brånemark System implant products that are the subject of this 510(k) are threaded, root-form implants fabricated from commercially pure titanium, either machined or modified (TiUnite™) surface, and are already commercially available.
Intended Use	The intended use of the Brånemark System Implants is for restoring chewing function by serving as anchorage for dental restorations.

Indications for Use	The Brånemark System implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Brånemark System implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.
Technological Characteristics	The technological characteristics of the Brånemark System implants remain substantially unchanged. No design modifications were made that effect safety and effectiveness.
Performance Data	Clinical results show that the expanded Indications for Use are as safe and effective as the original Indications for Use.
Conclusion	Based on the 510(k) summaries, 510(k) statements and the information provided herein, we conclude that the expanded Indications for Use are substantially equivalent to the currently marketed devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nobel Biocare AB
Ms. Kathleen Dragovich
Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22715 Savi Ranch Parkway
Yorba Linda, California 92887

OCT 11 2002

Re: K022562
Trade/Device Name: Various Brånemark System Implants-Immediate Function Indication
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: III
Product Code: 76 DZE
Dated: July 30, 2002
Received: August 2, 2002

Dear Ms. Dragovich:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022562

Section 1.5

Indications for Use Statement

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

Device Name: Various Brånemark System Implants - Immediate Function Indication

Indications for Use:

The Brånemark System implants are for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Brånemark System implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

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

Concurrence of CDHR, Office of Device Evaluation (ODE)

Prescription Use _____ (per 21 CFR 801.109) OR Over-the-Counter Use _____ Optional Format 1-2-96

Robert S Betz DDS for Dr Susan Runner

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

510(k) Number: K022562