

Pre-market Notification
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K974828

MAR 24 1998

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 titanium fixtures and two drills.

C. The Predicate Product

The predicate products used in this Pre-market Notification are other components marketed by Nobel Biocare which include the self-tapping MKII fixtures DCA 220, DCA 222, DCA 224, DCA 666, DCA 765 (K945398).

D. Description of Device

The Nobel Biocare **Ebon Fixture™** is an endosseous implant made of grade 1 commercially available titanium and is intended to be placed in the upper or lower jaw bone to support prosthetic devices such as artificial teeth and to restore the patient's chewing function. This system also includes 2 bevel drills.

E. Intended Use of the Device

Nobel Biocare's **Ebon™ Fixtures** are titanium endosseous implants that are intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth and to restore the patients chewing function. This fixture is not intended for use in Type I bone.

F. Comparison of Technological Characteristics

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Betsy A. Brown
Vice President, Regulatory Affairs
Nobel Biocare USA, Incorporated
777 Oakmont Lane, Suite 100
Westmont, Illinois 60559

MAR 24 1998

Re: K974828
Trade Name: Branemark System® Ebon™ Fixture
Regulatory Class: III
Product Code: DZE
Dated: December 23, 1997
Received: December 24, 1997

Dear Ms. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

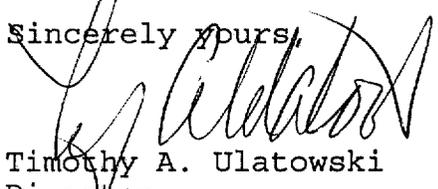
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the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Branemark System® Ebon Fixture

Indications For Use:

Nobel Biocare's Ebon™ Fixtures are titanium endosseous implants that are intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth and to restore the patient's chewing function. This fixture is not intended for use in type I bone.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number KA 7452

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)