K970499

OCT 16 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. Their telephone number is: (630) 654-9100, extension 2002, and the contact person will be Betsy Brown, the Director, Regulatory Affairs.

B. Name of the Device

This device consists of fixtures and numerous components to be used in conjunction with the BRÅNEMARK SYSTEM® Zygomaticus Fixture System, including Fixtures, Drills, Hand Instruments, Cover Screws and accessories specific to the Zygomaticus Fixture System.

C. The Predicate Product

The predicate products used in this Premarket Notification are other components marketed by Nobel Biocare including the Fixtures, K925762, Drills, K925770, Fixture Mount, K925775, Cover Screws, K925771, and Hand Instruments, K925774, K925483 and a tray, K953774. The predicate products also include a Drill Guide, K951510 which is manufactured by Ace Surgical Supply Co.

D. Description of the Device

The Nobel Biocare BRÅNEMARK SYSTEM® Zygomaticus Fixture System is an endosseous implant with components made of titanium intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth, and to restore the patient's chewing function. The system includes Fixtures, Drills, Hand Instruments, Cover screws and accessories.

E. Intended Use of the Device

The Nobel Biocare BRÅNEMARK SYSTEM® Zygomaticus Fixture System is intended to be used as an endosseous implant to be surgically placed in the upper jaw to support prosthetic devices such as artificial teeth and to restore a patient's chewing function.

F. Comparison of Technological Characteristics

The technological characteristics between the components of Zygomaticus Fixture System and the corresponding predicate products, comparable components in the BRÅNEMARK SYSTEM® and the drill guide manufactured by Ace Surgical Supply Co. are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

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

OCT 16 1997

Re: K970499
Trade Name: Branemark System Zygomaticus Fixture System
Regulatory Class: III
Product Code: DZE
Dated: July 18, 1997
Received: July 23, 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 (Premarket 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 premarket notification submission does not affect any obligation you might have under sections 531

through 542 of 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) 594-4618. 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: Zygomaticus Fixture System

Indications For Use:

The Nobel Biocare Brånemark System - Zygomaticus Fixture System is an endosseous implant with components made of titanium intended to be placed in the upper jaw arch to provide support for prosthetic devices such as artificial teeth, and to restore the patient's chewing function. The system includes Fixtures, Drills, Hand Instruments, Cover Screws and Accessories.

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

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 K970491

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

(Optional Format 1-2-96)