

MAY 26 1998

Center for Devices and Radiological Health
September 24, 1997
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K974123

Summary of Safety and Effectiveness

A. Name and Address

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

B. Name of the Device

This device is generally known as an accessory to a bone cutting instrument with the trade name "**Nobel Biocare Branemark System® DEC 600 Drilling Unit.**"

C. The Predicate Product

The predicate product used in this Premarket Notification is the Branemark System® Drill Equipment DEC 500 handpiece subject to premarket Notification K905436.

D. Description of the Device

The Nobel Biocare **Branemark System® DEC 600 Drilling Unit** is intended for use in oral and maxillofacial surgery including preparing sites for implantation of an endosseous implant fixture.

E. Intended Use of the Device

The Nobel Biocare **Branemark System® DEC 600 Drilling Unit** is intended to be used in oral and maxillo-facial surgery including placement of the Branemark System® endosseous implant. It is intended to be used to drill into the upper or lower jaw to prepare placement of an endosseous fixture, in the threading and mounting of fixtures, while drilling measure and record torque resistance for bone quality as well as to tighten cover and abutment screws.

F. Comparison of Technological Characteristics

The technological characteristics between the DEC 600 Drilling Unit and the predicate product are similar and the intended use is the same. Both products are used for oral and maxillofacial surgery and are used for cutting, drilling and shaping jaw bone.



MAY 28 1998

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

Re: K974123
Trade Name: Branemark System® Dec 600 Drilling Unit
Regulatory Class: III
Product Code: DZE
Dated: February 25, 1998
Received: February 25, 1998

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 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). 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.

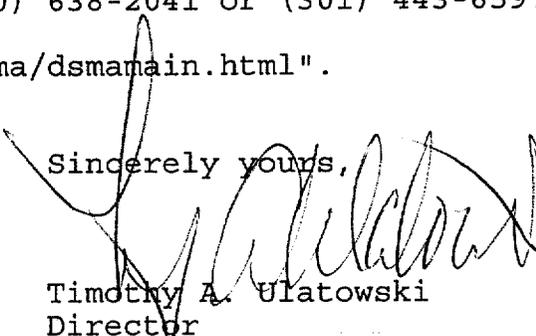
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, 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) 594-4692. 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" (21CFR 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/dsma/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: Brånemark System® DEC 600 Drilling Unit

Indications For Use:

The Nobel Biocare's **Brånemark System® DEC 600 Drilling Unit** is intended to be used in oral and maxillo facial surgery including placement of the Brånemark System endosseous implants. It is intended to be used to drill into the upper or lower jaw to prepare placement of an endosseous fixture, in the treading and mounting of fixtures, while drilling measure and record torque resistance for bone quality, as well as to tighten cover and abutment screws.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR
Susan Rente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

Over-The-Counter Use _____

510(k) Number 1974123

(Optional Format 1-2-96)