FEB 29 2000

Nobel Biocare USA, Inc.
510(k) Notification: Immediate Loading Indication
June 21, 1999

K992937

Section 7
510(k) Summary

A. Manufacturer Information:

Submitter's Name:	Nobel Biocare USA, Inc.
Address:	
U.S. Representative/Distributor	22725 Savi Ranch Parkway Yorba Linda, CA 92887, USA
Contact's Name:	Jeff Hausheer, Ph.D., Regulatory Affairs Specialist
Contact's Telephone No.:	714-282-4800, extension 7832
Date Prepared:	June 1999
Address-Manufacturer:	Nobelpharma Production AB Dimbovagen 2 Karlskoga S-691-51, Sweden

Manufacturer Registration Number: 9611993

B. Device Name:

Common Name: Dental Implant

Trade Name: Brånemark System® Implants Indicated For Loading Immediately Following Implant Placement (see table below) (i.e., within 2 to 3 weeks following implant placement)

Brånemark System®: Implant Product Family Name	Dimensions: Diameter & Range of Lengths (mm)
Standard Series Implants (3.75)	3.75 x 10-20 mm
Standard Series Implants (4.0)	4.0 x 10-18 mm
Mk II Self-Tapping Implants (3.75)	3.75 x 10-18 mm
Mk II Self-Tapping Implants (4.0)	4.0 x 10-18 mm
Self-Tapping Implants	3.75 x 10-18 mm
Conical Self-Tapping Implants	3.75 x 13-21 mm
Mk IV Self-Tapping Implants	4.0 x 10-18 mm

Classification:

Classification Name:	Endosseous Dental Implant
Classification Number:	DZE
Classification Citation:	21 CFR 872.3640

Section 7
510(k) Summary (continued)

C. Device Description:

Description: Brånemark System® dental implants are threaded, root-form implants fabricated from ASTM grade 1 "commercially pure" titanium. They are available in diameters of 3.75 mm and 4.0 mm, and are available in lengths ranging from 10 mm to 21 mm. Research studies have demonstrated that titanium is biocompatible.

D. Intended Use:

Indications For Use: Selected Brånemark System® implant products (those identified in Table 7.1, below) are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

If a single stage surgical procedure is used, these implants may be loaded immediately following insertion - PROVIDED – at least four implants are placed, and are splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foramina) where good initial stability of the implants, with or without bi-cortical anchorage, can most often be obtained.

Table 7.1
510(k) Notification:
Brånemark System® Implant Products Indicated For Immediate Loading

Brånemark System®: Implant Product Family	Diameter	Range of Lengths	510(k)
Mk II Self-Tapping	3.75 mm	10-18 mm	K925762
Mk II Self-Tapping	4.0 mm	4.0 x 10-18 mm	K945398
Standard Series	3.75 mm	3.75 x 10-20 mm	K925765
Standard Series	4.0 mm	4.0 x 10-18 mm	K925764
Self-Tapping	3.75 mm	3.75 x 10-18 mm	K925762
Conical Self-Tapping	3.75 mm	3.75 x 13-21 mm	K925760
Mk IV Self-Tapping	4.0 mm	4.0 x 10-18 mm	K974828

Section 7: 510(k) Summary (continued)

E. Comparison to the Predicate Device(s):

Comparison Of The Predicate Devices And The *Brånemark System*® Implant Products For Which Clearance Of An Immediate Load Indication Is Sought

	Predicate Product	Predicate Product	Submitted Product
Characteristic	Straumann ITI Implant (510(k) K984104)	Sargon Cylindro-Blade Implant [510(k) K930071]	Brånemark System® Implant Products**
Intended Use	intended to be placed in the maxillary and/or mandibular arches to support prosthetic restorations in edentulous or partially edentulous patients.	Intended to act as a replacement for missing teeth by providing the means for fixation of dentures, removable bridgework, or prosthetic teeth.	(Functionally, the same): intended to be placed in the upper or lower jaw to support prosthetic devices such as artificial teeth, and to restore patient's chewing function.
Indication	Immediate Load	Immediate Load	Same
Design	threaded, root-form implant	a threaded, tapered, non-solid (hollow), flanged root form implant	threaded, root-form implants
Placement Method	Single stage surgery	Single stage surgery	Same
Material	Commercially pure titanium	Titanium alloy	Commercially pure titanium
Coating	None	None	None
Length (mm, min.-max.)	Unknown	10mm to 18 mm	10mm to 21 mm
Diameter (mm)	Unknown	Available in 1 tapered design only, ran Available in one tapered design only; its diameter ranges from 3.8 mm to 4.1 ranging from 3.8 mm to 4.1 mm	3.75 mm and 4.0 mm
Precautions & Warnings	Unknown	None	None
Packaging	Unknown	Vial	Glass ampoule in peel-open blister pack
Provided Sterile?	Unknown	Unknown	Yes (dry heat = glass ampoule; steam = blister pack)

= See Table 2.A.1 for identification, dimensions, and 510(k) numbers of each product

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2000

Dr. Jeff Hausheer
Regulatory Affairs Specialist
Nobel Biocare USA, Inc.
22895 Eastpark Drive
Yorba Linda, CA 92887

Re: K992937
Trade Name: Brånemark System® Implants
Regulatory Class: III
Product Code: DZE
Dated: December 2, 1999
Received: December 6, 1999

Dear Dr. Hausheer:

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 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 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) 594-4690. 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

Section 10
Indications for Use

510(k) Number (if known): K------

Device Name:

Selected Brånemark System® Implant Products:

Mk II Self-Tapping	K925762
Mk II Self-Tapping	K945398
Standard Series	K925765
Standard Series	K925764
Self-Tapping	K925762
Conical Self-Tapping	K925760
Mk IV Self-Tapping	K974828

Indications For Use: Selected Brånemark System® implant products (those identified in the preceding section, "Device Name") are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

If a single stage surgical procedure is used, these implants may be loaded immediately following insertion - PROVIDED – at least four implants are placed, and are splinted with a bar. These implants must be placed predominantly in the anterior mandible (between the mental foramina) where good initial stability of the implants, with or without bi-cortical anchorage can most often be obtained.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K992237