

JAN 28 2000

K993595

Nobel Biocare USA, Inc.
510(k) Notification: Modified Surface Implant (Immediate Loading Indication)
October 18, 1999

Section 8
510(k) Summary

Nobel Biocare USA Letterhead

510(k) Summary

A. Manufacturer Information:

Submitter's Name: Nobel Biocare USA, Inc.

Submitter's Address (U.S. Representative/Distributor):
22825 Eastpark Drive
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: October 1999

Address (Manufacturer): Nobelpharma Production AB
Dimbovagen 2
Karlskoga S-691-51
SWEDEN

Manufacturer's Registration No. 9611993

B. Device Name:

Common Name: Dental Implant

Trade Name: Nobel Biocare's Modified Surface Implant

C. Classification:

Classification Name: Endosseous Dental Implant

Classification Number: DZE

Classification Citation: 21 CFR 872.3640

Section 8
510(k) Summary (continued)

D. Device Description:

Nobel Biocare's Modified Surface Implant is a threaded, hex-lock root-form dental implant. It is 3.75-mm in diameter and is available in lengths ranging from 7-mm to 20-mm. The surface of the threaded portion of the implant has a titanium oxide layer that is uniformly thin (mean 10μ, range = 3μ to 10μ).

E. Intended Use:

Nobel Biocare's Modified Surface Implant is 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 the single stage 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.

F. Comparison to the Predicate Device(s):

The following table provides a comparison of the technological characteristics of the predicate devices and Nobel Biocare's Modified Surface Implant

Section 8
510(k) Summary (continued)

Table 8.1
Identification of the Predicate Devices and the Submitted Device, Nobel Biocare's Modified
Surface Implant

Implant Product	510(k) # (and Manufacturer)
Modified Surface Implant	K # pending
Cylindro-Blade Implant	K930071 (Sargon)
ITI "One Part" Implant	K984104 (Straumann)

Section 8
510(k) Summary (continued)

Table 8.2

Technology: Comparison of the Predicate Devices and the Submitted Device, Nobel Biocare's Modified Surface Implant

Attribute/ Characteristic	Predicate No. 1 Sargon Cylindro-Blade Implant	Predicate No. 2 Strau- mann ITI Implant	Nobel Biocare's Modified Surface Implant (Submitted Product)
Design	Threaded, tapered, non-solid (hollow), flanged root-form implant	Threaded, root-form	SAME predicate #2)
Placement Method	Single stage surgery, immediate load	Single stage surgery, immediate load	SAME
Body Material	Titanium alloy	Commercially pure tita- nium	SAME (predicate #2)
Coating	None	None	SAME
Length (mm, min.- max.)	10 mm to 18 mm	Unknown	7 mm to 20 mm*
Diameter (mm)	Available in 1 tapered design only; its di- ameter ranges from 3.8 to 4.1 mm.	Unknown	3.75 mm
Packaging	Vial	Unknown	Glass vial in blister pack
Sterility	Unknown	Unknown	Sterile

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist
Nobel Biocare USA, Incorporated
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K993595
Trade Name: Nobel Biocare's Modified Surface Implant
Regulatory Class: III
Product Code: DZE
Dated: October 22, 2000
Received: October 25, 2000

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.

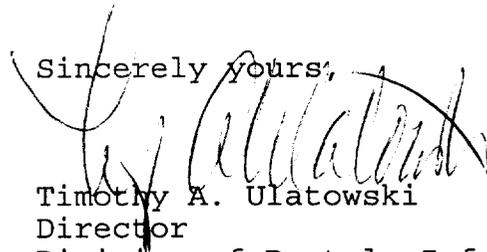
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Dr. Hausheer

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

K993595

Nobel Biocare USA, Inc.
510(k) Notification: Modified Surface Implant (Immediate Loading Indication)
October 18, 1999

Section 1
Indications for Use

Page 1 of 1

510(k) Number (if known): K9XXXXX

Device Name: Nobel Biocare's Modified Surface Implant

Indications For Use:

Nobel Biocare's Modified Surface Implant is 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 the single stage 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)

Donald W. Sheppard for MSR

(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K993595 NOBEL BIOCARE USA - OCTOBER 1999

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