March 1, 1999

K984287

Nobel Biocare

March 1, 1999

Food and Drug Administration
CDRH, ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Attention: Angela Blackwell, Dental Devices Branch

Re: 510(k) K984287
Nobel Biocare's "Immediate Provisional Implant"

Dear Ms. Blackwell:

Enclosed are two original copies of Section 7, 510(k) K984287, Immediate Provisional Implant, revised to reflect changes to the 510(k) that you, as the reviewer, had requested.

If you require any other information, please let me know.

Sincerely,

Jeff Hausheer, Ph.D.

Jeff Hausheer, Ph.D.
Regulatory Affairs Specialist
Nobel Biocare USA

Encl.: Section 7 (revised), 510(k) K984287, Immediate Provisional Implant

cc: P. Gasser
510(k) file K984287
K. Rendon

Nobel Biocare USA, Inc. 22895 Eastpark Drive, Yorba Linda, CA 92887
Telephone (714) 282-4800 (800) 993-8100
Fax (714) 998-9236

Original 510(k)
Immediate Provisional Implant

Section 7
510(k) Summary

Manufacturer Information:

Submitter's Name:	Nobel Biocare USA
Address:	22895 Eastpark Drive Yorba Linda, CA 92887 U.S.A.
Contact's Name:	Jeff Hausheer, Ph.D. Regulatory Affairs Specialist
Telephone Number:	714-282-4800, extension 7832
Date Prepared:	March 1999

Device Names:

Common Name:	Dental Implant
Trade Name:	Immediate Provisional Dental Implant System
Classification Name:	Endosseous Implant

Predicate Device:

Substantial equivalence is claimed to Dentatus' "MTI Implant" and Sendax's "Mini Dental Implant".

Device Description:

Nobel Biocare's "Immediate Provisional Implant" is designed to provide temporary support for prosthetic devices during the healing phase of permanent root form implants.

Section 7
510(k) Summary (continued)

Device Description (continued):

Scientific concepts:

Natural dentition is composed of a subgingival root and a supragingival crown. Root form implant designs in existence are intended to mimic this structure, and to aid the patient by allowing restoration of natural masticastory function. During the period while permanent endosseous implants are healing, all loading of the permanent implants must be avoided. Consequently, patients have poor quality masticastory function, if any such function at all during the healing period.

Temporary provisional implants, placed concurrently with the permanent implants, and on which a provisional prosthesis can be placed, provide the patient masticastory function during the permanent implant-healing period, and protect the permanent implants from pre-mature loading and/or micromovement.

The "Immediate Provisional Implant" is designed to serve as a temporary root of the provisional artificial tooth, and the provisional abutment/prosthetic is designed to serve as the temporary crown. After the permanent implant-healing period is completed, the provisional prosthesis and temporary implants are removed, and a permanent abutment and prosthesis fitted to the permanent implants.

Characteristics:

Nobel Biocare's threaded titanium "Immediate Provisional Implant" is available in widths of 2.8 millimeters and 3.2 millimeters, and lengths ranging from 14 millimeters to 22 millimeters.

Section 7
510(k) Summary (continued)

Intended Use:

Nobel Biocare's "Immediate Provisional Implant" is indicated for use as a temporary support for provisional prosthetic devices during the healing phase of permanent endosseous dental implants.

Comparison to Predicate:

The following table (Table 7.1) provides a comparison of the technological characteristic of Nobel Biocare's "Immediate Provisional Implant" to the predicate provisional implants, Dentatus' MTI Implant and Sendax's Mini Dental Implant.

TABLE 7.1
Comparison of Nobel Biocare's "Immediate Provisional Implant"
to the Predicate Devices

Characteristic	Dentatus' MTI Implant	Sendax's Mini Dental Implant	Nobel Biocare's "Immediate Provisional Implant"
Body Material	Titanium	Titanium & Titanium alloy*	SAME (Titanium)
Geometry	Threaded	Threaded	SAME
Length	17 mm & 20 mm	14, 17, 19, and 22 mm	SAME (14 to 22 mm)
Diameter	1.8 mm	1.8 mm	2.8 mm & 3.2 mm**
Sterility	Non-sterile	Unknown	Sterile

* = Sendax's 510(k) cleared for both commercially pure titanium and titanium alloy
** = Nobel Biocare submitted clinical data supporting 2.8 mm and 3.2 mm.

Performance Data:

In a clinical trial, Nobel Biocare's "Immediate Provisional Implant" successfully provided support for provisional prosthetic devices while simultaneously protecting the permanent implants from premature loading during their healing period. Following healing of the permanent implants, the "Immediate Provisional Implants" were removed, abutments affixed to the permanent implants, and a permanent prostheses attached. Use of the Nobel Biocare "Immediate Provisional Implant" did not affect the success of the permanent implants and the associated permanent implant supported restorations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

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

Re: K984287
Trade Name: Provisional Dental Implant System
Regulatory Class: III
Product Code: DZE
Dated: November 20, 1998
Received: December 1, 1998

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) 594-4692. 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): K984287

DEVICE NAME: Provisional Dental Implant System

INDICATIONS FOR USE:

The intended use for this device is to serve as temporary support for provisional prosthetic devices during the healing phase of permanent endosseous dental implants.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K984287