K980460

MAY 5 1998

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. Our telephone number is: (630) 654-9100, extension 2002, and the contact person will be Betsy Brown, the Vice President, Regulatory Affairs.

B. Name of the Device

This device consists of implants and numerous components to be used in conjunction with the **Onplant Orthodontic System™,** including implants, cylinders, abutments, orthodontic wire, cover screws, hand instruments, and accessories used in conjunction with the Onplant Orthodontic System.

C. The Predicate Product

The predicate products used in this Pre-market Notification are other components marketed by Nobel Biocare including the Cylinders, (K925776), Abutments and Abutment Screws (K925776), Cover Screws, (K925771),. Abutment Replica (K944964), Hand Instruments, (K925774 and K925772) as well as other orthodontic anchor devices such as the Linkow Blade Implant, which is marketed by Steri-Oss, and Orthodontic Wire (K935142) marketed by Dentaurum, and pre-amendment orthodontic wire marketed by Star Dental.

D. Description of the Device

The Nobel Biocare **Onplant Orthodontic System** is an implant with components made of titanium intended for subperiosteal placement in the palatal region of the mouth to provide an anchor for orthodontic procedures. The system includes Implants, Cylinders, Abutments, Orthodontic Wire, Hand Instruments, Cover Screws and accessories.

E. Intended Use of the Device

The Nobel Biocare **Onplant Orthodontic System** is an implant intended to be surgically placed subperiosteal in the palatal region of the mouth for use as an anchor for orthodontic procedures in patients who have completed skeletal growth and maturity.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 5 1998

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

Re: K980460
Trade Name: Onplant Orthodontic System™
Regulatory Class: III
Product Code: DZE
Dated: February 2, 1998
Received: February 2, 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 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):_____

Device Name: ____Onplant™ Orthodontic System

Indications For Use:

The Nobel Biocare Onplant Orthodontic System is an implant intended to be surgically placed subperiosteal in the palatal region of the mouth for use as an anchor for orthodontic procedures in patients who have completed skeletal growth and maturity.

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

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 K980460

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

(Optional Format 1-2-96)