NOV 18 1998

K983453

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. The 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

The device is a glass powder used to fuse the sections of a dental bridge together. The dental bridge sections consists of densely sintered, high purity aluminum oxide copings and a pontic, which Porcelain All Ceram is applied to the surface.

C. The Predicate Product

The predicate products used in this Pre-market Notification are Vita In-Ceram (K#913644) Manufactured by Vident and Gdc-3338, Dental Solder Alloy (K#920887) manufactured by J.M. Ney.

D. Description of Device

The Nobel Biocare **Procera® All Ceram Fusing Material** is a glass powder, which is combined with distilled water to produce a mixture of "pasty" consistency. The Procera fusing material is used to fuse together the sections of a dental bridge. The dental bridge sections consists of densely sintered, high purity aluminum oxide copings and a pontic. Procera® AllCeram Porcelain is then applied to the surface of the dental bridge structure.

E. Intended Use of the Device

Nobel Biocare's **Procera® AllCeram Fusing Material** is a glass based powder which is mixed with distilled water. It is intended to be used to fuse together the sections of an aluminum oxide dental bridge.

F. Comparison of Technological Characteristics

The technological characteristics between the components of the **Procera® AllCeram Fusing Material** and the corresponding predicate products, Vita InCeram by Vident and Gdc 3338 Dental Solder Alloy by J.M. Ney are equivalent.

VIII. Substantial Equivalence

The Nobel Biocare **Procera AllCeram Fusing Material**, is a glass based powder, which is mixed with distilled water to create a fusing material for the sections of an aluminum oxide dental bridge. The aluminum oxide bridge is comprised of two copings and a pontic. To create the dental bridge using the Procera fusing material, the dental laboratory technician makes a refractory model from the patient's dental impression. The copings are placed on the refractory model with the pontic positioned between. Next the Procera fusing material is mixed with the appropriate amount of distilled water to form a "pasty" mixture, which is then applied to the occlusal surfaces of the dental bridge joints and allowed to air dry. One must sandblast the unfinished dental bridge at this point to remove any excess fusing material. Next Procera AllCeram Porcelain is applied to all surfaces of the bridge structure and then it is placed into a heated porcelain firing furnace.

Nobel Biocare's **Procera AllCeram Fusing Material** is substantially equivalent to the commercially available In-Ceram (K#913644) in that these products have essentially identical compositions and they are both used in the construction of dental bridges. The Procera AllCeram Fusing Material is also believed to be substantially equivalent to the Gdc 3338, Dental Solder Alloy (K#920887) in that both devices are used to "fuse" the various sections/components of a dental bridge, thus having the same intended use. Nobel Biocare's **Procera AllCeram Fusing Material** will be supplied in 5 gram, 10 gram, 20 gram and 40 gram quantities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K983453
Trade Name: Procera® All Ceram Fusing Material
Regulatory Class: II
Product Code: EIH
Dated: September 23, 1998
Received: September 30, 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): K983453

Device Name: Procera® AllCeram Fusing Material

Indications For Use:

Nobel Biocare's Procera® AllCeram Fusing Material is a glass based powder which is mixed with distilled water. It is intended to be used to fuse together the sections of an aluminum oxide dental bridge.

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

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 K983453

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

(Optional Format 1-2-96)