K993249

NOV 29 1999

20.0 510(K) SUMMARY

OPC Low Wear Opaque Porcelain will be used for porcelain-fused to metal restorations on high expansion alloys by or on the order of a dentist. OPC Low Wear Opaque Porcelain contains opacifiers to cover the metal on porcelain-fused to metal restorations. OPC Low Wear Opaque Porcelain is to be used on patients in a dentist office environment. We believe that OPC Low Wear Porcelain, K982377, and Synspar Porcelain, K910303, which have previously been approved by the FDA, are substantially equivalent. These devices are powder porcelains used for fabricating restorations. OPC Low Wear Opaque Porcelain only differs from OPC Low Wear Porcelain, K982377, and Synspar Porcelain, K910303, due to opacifiers being added to hide the metal of the restorations. Also, Zinc oxide has also been added to help achieve adequate bond to the metal. Zirconium, Titanium and Zinc are all present in the porcelain as oxides, which renders them inert. The safety and effectiveness is not affected because OPC Low Wear Opaque Porcelain only differs from the predicate devices by adding opacifiers to hide the metal of the restorations and Zinc Oxide help achieve adequate bond to the metal. OPC Low Wear Opaque Porcelain also contains Fluorine as does OPC Low Wear Porcelain, K982377.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 29 1999

Ms. Annmarie Tenero
Jeneric®/Pentron® Incorporated
53 North Plains Industrial Road
P.O. Box 724
Wallingford, Connecticut 06492-0724

Re: K993249
Trade Name: OPC Low Wear Opaque Porcelain
Regulatory Class: II
Product Code: EIH
Dated: September 27, 1999
Received: September 28, 1999

Dear Ms. Tenero:

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): K993249

DEVICE NAME: OPC Low Wear Opaque Porcelain

INDICATIONS FOR USE: **OPC Low Wear Opaque Porcelain is a porcelain powder, which will be bonded to metal copings to form dental restorations. Subsequent layers of translucent porcelains will be fired on top to complete the restoration. Particularly, to be used with OPC Low Wear Porcelain, K982377 to cover the metal restoration.**

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K993249