

K994435

21.0 510(K) SUMMARY

Submitter: Jeneric/Pentron, Inc.
Address: 53 North Plains Industrial Road
Wallingford, Connecticut 06492
Contact Tel: 203-265-7397 X619
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Contact Person: Annmarie Tenero

Date Summary Prepared: May 26, 2000

The compositions for 3G All-Ceramic Core is similar to Finesse All-Ceramic Core, K971869, Dentsply International and Empress2 Core, K982616, Ivoclar North America, in both composition and function. Likewise, the 3G All Ceramic overlay used in conjunction with the 3G Core is also similar to the overlay porcelains for these same cores, Finesse Porcelain and Empress2 Porcelain. Because of these similarities to predicate devices, the material is substantially equivalent.

The OPC 3G All-Ceramic System, Core and Overlay Porcelains comprise a lithium disilicate glass-ceramic core used for all-ceramic dental restorations. Subsequent layers of porcelain are applied over top to provide additional aesthetics and characterizations. This system offers high strength, low wear, the aesthetics of a metal-free system, and better thermal shock properties due to the lower thermal expansion of the materials used.

The dental restoration is prepared by a lost wax technique. The dental restorations are designed in a wax pattern and invested into refractory. The refractory is burned out to remove the wax and leave a cavity of the dental design. Pellets of 3G All-Ceramic are placed into the investment cavity and transferred to a hot pressing furnace where the investment/pellets are brought to a higher temperature. The temperature is maintained long enough for the glass-ceramic to become molten and then pressed into the cavity creating an exact duplicate of the original wax pattern.

In addition, dental restorations can be made by forming the material into pre made blocks of ceramics, which are milled to the coping/bridge shape by CAD/CAM equipment.

The OPC 3G All-Ceramic System is intended for either hot pressing or CAD/CAM machining all-ceramic dental restorations. The 3G All-Ceramic System should be used with 3G All-Ceramic materials only and not intermixed with other manufacturers products/porcelains. The system is used for fabrication of dental restorations including inlays, onlays, veneers, single units, and anterior bridges up to the first premolar.

The OPC 3G All-Ceramic System, Core and Overlay Porcelains will include Core pellets, Core Stains, Bodies, Incisals, Glazes, Investment, Investment Liquids, Acid Solutions (Shipped Separately), Acid Neutrilizers, Glaze Liquids, Disposable Plungers, Paper Rings, Plastic Scoops, MSDS and Instructions.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 2000

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

Re: K994435
Trade Name: OPC 3G All-Ceramic System, Core and Overlay
Porcelains
Regulatory Class: II
Product Code: EIH
Dated: December 28, 1999
Received: December 30, 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 (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 premarket notification submission does not affect any

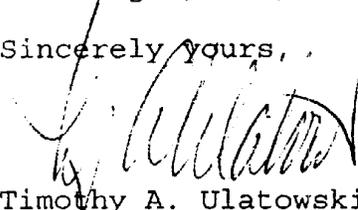
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K994435

DEVICE NAME: OPC 3G ALL-CERAMIC SYSTEM, CORE AND OVERLAY PORCELAINS.

INDICATION FOR USE:

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Sund...
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994435

(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)

5.0

Jeneric/Pentron, Inc.

510K Submission – OPC 3G ALL-CERAMIC SYSTEM, CORE AND OVERLAY PORCELAINS