AUG 2 3 2001

K012231

21.0 510(K) SUMMARY

Submitter: **Jeneric/Pentron, Inc.**
Address: **53 North Plains Industrial Road**
Wallingford, Connecticut 06492
Contact Tel: 203-265-7397 X619
Contact Fax: 203-265-7662
Contact Person: Annmarie Tenero

Date Summary Prepared: July 12, 2001

Avante Micro Crystal System is a porcelain-fused-to-metal (PFM) restorative system to be layered on conventional PFM alloys to make crowns and multiple-unit bridges. The porcelains can also be used with refractory or foil to create veneer restorations.

The composition of Avante Porcelain is similar to that of Synspar Porcelain, K910303. The relative proportion of certain elements was adjusted in Avante Porcelain to result in a lower firing temperature compared to Synspar. However, the actual list of chemical compounds present in Avante is similar to that of Synspar.

The lower firing temperature of Avante compared to the predicate material has no affect on safety and effectiveness of the material. The properties of the material that make it safe and effective for use will be obtained if properly fired according to the user instructions provided with this product.

Cytotoxcity testing was not performed due to the similarity of this device in composition to the other products currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2001

Ms. Annmarie Tenero
Jeneric/Pentron, Incorporated
53 No. Plaines Industrial Road
Wallingford, Conecticut

Re: K012231
Trade/Device Name: Avante Micro Crystal System
Regulation Number: 872.6660
Regulatory Class: II
Product Code: EIH
Dated: July 12, 2001
Received: July 16, 2001

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 legally marketed predicate 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/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

K012231

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K012231

DEVICE NAME: AVANTE MICRO CRYSTAL SYSTEM

INDICATION FOR USE:
Avante Micro Crystal System is a porcelain-fused-to-metal (PFM) restorative system to be layered on conventional PFM alloys to make crowns and multiple-unit bridges. The porcelains can also be used with refractory or foil to create veneer restorations.

MGaylor for NBR

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital
510(k) Number K012231

(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)**