K001623

JUL 11 2000

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: May 25, 2000

Sculpture Flow is a light cured flowable restorative composite in syringe form used to restore a crown or missing tooth. Sculpture Flow is substantially equivalent to the Crown & Bridge Dental Restorative Composite System, K894644, Jeneric/Pentron. Both Sculpture Flow and Crown & Bridge Restorative Composite System, K984644 are light cured and are used to restore a crown or missing tooth. The only difference between Sculpture Flow and Crown & Bridge Dental Restorative Composite System is filler content percentages to allow Sculpture Flow to be flowable for easier application. Since the same materials found in Sculpture Flow are also widely used in other products currently on the market, Biocompatibility testing was not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2000

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

Re: K001623
Trade Name: Sculpture Flow
Regulatory Class: II
Product Code: EBF
Dated: May 25, 2000
Received: May 26, 2000

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

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K001623

DEVICE NAME: SCULPTURE FLOW

INDICATION FOR USE: Sculpture Flow is a light cured flowable restorative composite in syringe form used to restore a crown or missing tooth.

(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** ____

(Division Sign-Off) ~~(Optional Format 1-2-96)~~ 5.0

Division of Dental, Infection Control, and General Hospital Devices

Susan Runner

510(k) Number K001623

Jeneric/Pentron, Inc.
510K Submission – SCULPTURE FLOW