MAR 2 1 2000

K994389

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: March 14, 2000

Bond 1 C&B is substantially equivalent to Bond 1, K973388. Bond 1 C & B is used for adhesion to dentin and bonding of various polymeric filling materials (composites). Also, Bond 1 C & B is used with other conditions for bonding of composite to metal including, amalgam, gold, semi precious, and non precious alloys, porcelain and glass and luting of same to Dentin and Enamel.

Bond 1 C&B contains Alcohol and Bond 1 K973388 contains Acetone. Bond 1 C&B will reduce the technique sensitivity of bonding, increasing the working time and decreasing the potential for sensitivity. However, some dentists prefer to use either Acetone or Alcohol.

The safety and effectiveness is not affected due to Alcohol being used in Bond 1 C&B instead of Acetone, which Bond 1 contains. This will reduce the technique sensitivity bonding, increasing the working time and decreasing the potential for sensitivity.

No clinical performance investigations were conducted on Bond 1 C & B since it is substantially equivalent to Bond 1, K973388. Cytoxicity studies will be furnished upon request. Materials in Bond 1 C&B are known in the industry.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2000

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

Re: K994359
Trade Name: Bond 1 C&B
Regulatory Class: II
Product Code: KLE
Dated: March 3, 2000
Received: March 13, 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

MAR 21 2000

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) 594-4690. 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

K994359

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K994359

DEVICE NAME: BOND 1 C& B

INDICATION FOR USE:

Bond 1 C & B is used for adhesion to dentin and bonding of various polymeric filling materials (composites). Also, Bond 1 C & B is used for bonding of composite to metal, including amalgam, gold, semi precious, and non precious alloys, porcelain and glass and luting of same to Dentin and Enamel.

(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) 5.0

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994359