K021457

AUG 01 2002

21.0 510(K) SUMMARY

Flex Span Temporary Crown & Bridge Material is intended to be used to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated. We believe that Flex Span Temporary Crown & Bridge Material is substantially equivalent to Sybron Dental Specialties, Inc. Temphase, K020092. Flexspan Temporary Crown and Bridge Material is to be used on dental patients in a dental office environment. Flexspan has the capability of being dual-cured, ie, visible light cure and/or self-cured. The optional light curing ability will give the dentist a choice of not waiting too long for the material to fully cure, if there is a need to fasten the hardening of the material. Cytotoxicity test has been performed. Furthermore, all the ingredients used in the formulation are widely used in dental industry and in our own composite compositions, which are known to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Annmarie Tenero
Pentron Corporation
53 North Plains Industrial Road
P.O. Box 724
Wallingford, Connecticut 06492

AUG 0 1 2002

Re: K021457
Trade/Device Name: Flex Span Temporary Crown & Bridge Material
Regulation Number: 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 3, 2002
Received: May 6, 2002

Dear Ms. Tenero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 Part 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 Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATION FOR USE STATEMENT

510(k) NUMBER (IF KNOWN): K021457

DEVICE NAME: Flex Span Temporary Crown & Bridge Material

INDICATION FOR USE:

Flex Span Temporary Crown & Bridge Material is intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated.

(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 K021457