FEB 1 1 2005

K050180

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: January 2005

Device Name:

- Trade Name - *Expa-syl*
- Common Name - Gingival Retraction/Hemostatic Paste
- Classification Name - Unclassified

Devices for Which Substantial Equivalence is Claimed:

- Coltene/Whaledent, *Stay-put Impregnated*
- Ultradent Products, Inc., *Ultrapak E*

Device Description:

Expa-syl is a paste containing aluminum chloride which is used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam. The paste is extruded through the tip attached to the cartridge and applied into the sulcus through the use of the manual dispensing gun. The paste is left in place between 1 to 2 minutes, depending upon the tonicity of the marginal gingiva, and then removed by an air and water spray with simultaneous aspiration. A dry, retracted sulcus is obtained.

Intended Use of the Device:

The intended use of *Expa-syl* is for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Substantial Equivalence:

Expa-syl is substantially equivalent to other legally marketed devices in the United States. *Expa-syl* functions in a manner similar to and is intended for the same use as the products *Stay-put Impregnated* and *Ultrapak E* cleared for marketing for Coltene/Whaledent and Ultradent Products, Inc., respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Produits Dentaires Pierre Rolland
C/O Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K050180
Trade/Device Name: Expa-Syl™
Regulation Number: N/A
Regulation Name: Retraction Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: January 24, 2005
Received: January 26, 2005

Dear Ms. Boswell:

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.

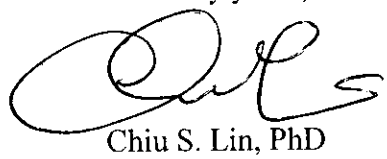
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050180

Device Name: *Expa-syl*

Indications For Use:

Expa-syl is a paste containing aluminum chloride which is intended to be used for the temporary retraction and hemostasis of the gingival margin during dental procedures such as, but not limited to, dental impressions, seating of temporary and permanent restorations, restorations of cavities and placement of a rubber dam.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K050180