510(k) Submission
Stay-put impregnated
510(k) Summary

JUN 1 5 2004

K041023

This summary of 510 (k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR § 807.92.

1. The submitter of this premarket notification is:

Coltène/Whaledent Inc.
Henry Vogelstein
235 Ascot Parkway
Cuyahoga Falls, OH 44223-3701
USA
Tel.: (212) 289-4748
Fax: (212) 289-4748

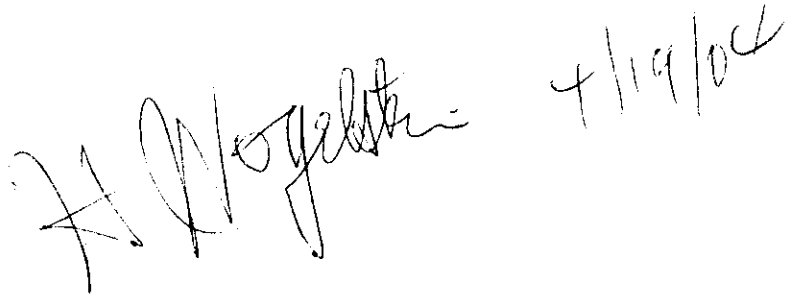
This summary was prepared on February 20, 2004

2. The name of this device is Stay-put impregnated. Its common name is Stay-put impregnated and its classification is retraction cord.

3. Stay-put impregnated is substantially equivalent to Ultrapak E manufactured by Ultradent Products Inc.

4. Stay-put impregnated is a retraction cord with a metal core and impregnated with Aluminium chloride Hexahydrate.

5. The technical characteristics are similar to those found with the predicate device Ultrapak E. Both products are impregnated retraction cords for dental use. Differences are only in the compression aid.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2004

Coltene/Whaledent Incorporated
C/O Mr. Henry J. Vogelstein
Official Correspondent Designated U.S. Agent
1349 Lexington Avenue
New York, New York 10128

Re: K041023
Trade/Device Name: Stay-Put Impregnated
Regulation Number: N/A
Regulation Name: Retraction Cord
Regulatory Class: Unclassified
Product Codes: MVL
Dated: April 19, 2004
Received: April 20, 2004

Dear Mr. Vogelstein:

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 (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) you may obtain. 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,

Anthony D. Watson for

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

coltène whaledent

Indications for Use

510(k) Number (if known): K041023

Device Name: Stay-put impregnated

Indications for Use:

Stay-put impregnated are polyester cords impregnated with aluminium chloride hexahydrate for the temporary retraction and haemostasis of the gingival margin.

Prescription Use ____X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 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: K041023