K060335

FEB 2 4 2006

510K SUMMARY

SUBMITTED BY: ULTRADENT PRODUCTS, INC.
505 WEST 10200 SOUTH
SOUTH JORDAN, UTAH 84095

CONTACT PERSON: Tammy Lavery
RA Senior Manager
Phone: 1-801-553-4323

DATE PREPARED: 12-05-05
TRADE NAME: File-Eze
COMMON NAME: Root Canal Cleanser
CLASSIFICATION: Unclassified
PREDICATE DEVICE: RC-PREP - Pre-1976 Device

DEVICE DESCRIPTION: File-Eze is a 19% EDTA dentin chelating agent in an aqueous, water-soluble solution with a lubricating base. File-Eze is irrigated and rinsed from canal as with other root canal preparations; ChlorCid and ChlorCid V (more viscous) sodium hypochlorite solution works well for this. Also, a slight effervescent cleansing action occurs when ChlorCid contacts residual File-Eze which helps remove extraneous material from canal.

INTENDED USE: Use File-Eze to aid in instrumentation and debridement of root canals.

The intended use of File-Eze and the predicate device, RC-Prep are the same, i.e. the cleansing and preparation of the root canal.

The physical properties of File-Eze and the predicate device are similar, i.e. viscosity, appearance, color, and odor.

TECHNOLOGICAL CHARACTERISTICS: File-Eze and the predicate device have the same active ingredient and the same intended use.

We believe that File-Eze is similar to RC Prep and because of the long established safe and efficacious use of the predicate device in the same intended use, the same active ingredient, the short duration of contact within the oral cavity, and the thorough removal of the product from the canal space, that File-Eze is safe and effective for the intended use. Additionally, the results of the following two studies further demonstrate the safety and effectiveness of File Eze for its intended use:

A study was done utilizing SEM's comparing the removal of the dentin smear layer in root canal systems, the results show that File-Eze is similar in effectiveness compared to RC Prep. A biocompatibility study was done to evaluate cytotoxicity of File-Eze using the Agar Diffusion Method. The results of this study show that File-Eze is not cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 2006

Ms. Tammy Lavery
Regulatory Affairs Senior Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K060335
Trade/Device Name: File-Eze
Regulation Number: N/A
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: December 05, 2005
Received: February 09, 2006

Dear Ms. Lavery:

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/industry/support/index.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): K060335

Device Name: File-Eze

Indications for use:

Use File-Eze to aid in instrumentation and debridement of root canals.

Prescription Use: X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: ______
(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)

Kevin Mulry for MSR

...ology, General Hospital, ...Dental Devices

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