DEC 16 2005

K052263

510(k) SUMMARY
As required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICES

Ultradent UltraEZ is a 3% potassium nitrate and 0.11% fluoride ion gel desensitizer. The indication for this product is the relief of tooth discomfort caused by root sensitivity, thermal and chemical changes, periodontal conditions...etc.

DESCRIPTION OF THE APPLICANT DEVICE – TOOTH DESENSITIZER

Cosmedent TOOTH DESENSITIZER is a 3% potassium nitrate and 1200 ppm fluoride ion gel desensitizer. The indication for this product is tooth discomfort caused by dentine sensitivity.

TOOTH DESENSITIZER is a gel desensitizer device based on the well documented effects of potassium nitrate and fluoride ion on dentine sensitivity due to patent dentinal tubules.

TOOTH DESENSITIZER is available as a clear, green-colored, gel. It can be used either by gently brushing the affected area with the product or it can be used in a custom tray.

INTENDED USES OF THE APPLICANT DEVICE

TOOTH DESENSITIZER is intended to be used to relieve the discomfort from dentin sensitivity.

James L. Sandrik, PhD

Cosmedent, Inc.
401 N. Michigan Avenue
Suite 2500
Chicago, Illinois 60611
Submitted: August 16, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 2005

Mr. James L. Sandrik
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K052263
Trade/Device Name: Multiple (Tooth Desensitizer)
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: December 14, 2005
Received: December 15, 2005

Dear Mr. Sandrik:

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" (21CFR 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 Lin, Ph.D.
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):

Device Name: MULTIPLE (TOOTH DESENSITIZER)

Indications For Use:

- The product is used either by a dental professional in the dental office or by a patient at home to treat dentin sensitivity.

Prescription Use___X_____ 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

...Sign-Off)
...ion of Anesthesiology, General Hospital,
...tion Control, Dental Devices

...) Number K052263