ULTRADENT PRODUCTS, INC.

K061438

JUN 12 2007

SUMMARY REPORT AND STATEMENT OF COMPARISON

INTRODUCTION:

This summary of 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 and supports the conclusion of SE for **UltraEZ Desensitizing Gel** noted below.

1. Applicant's Name and Address:

Ultradent Products, Inc.
505 West 10200 South
South Jordan, Utah 84095
Telephone number: 801-553-4323
Fax number: 801-572-0600
Contact Person: Tammy Lavery
Regulatory Affairs Senior Manager

2. Device Information:

Classification:	Class II
Regulation:	872.3260
Trade Name:	UltraEZ Desensitizing Gel
Common Name:	Tooth Desensitizer
Classification Name:	Varnish, Cavity
Classification Code:	LBH
Classification Panel:	Dental

3. Indications for Use:

The UltraEZ Desensitizing Gel provides a film-like varnish for sensitive teeth, sealing dentinal tubules of over exposed dentin and other exposed areas where post-operative or other dentin sensitivity is a concern. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity.

4. Predicate Device Description & Statement of Comparison to Predicate Device:

UltraEZ Desensitizing Gel which is to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, Utah 84095, **is substantially equivalent to the legally - marketed device(s): Cosmedent Tooth Desensitizer** marketed by Cosmedent, Inc., 401 N. Michegan Avenue, Ste 2500, Chicago, IL 60611, and Protect marketed by Sunstar Butler Refer, 4635 West Foster Avenue, Chicago, IL 60630. Refer to the comparison table below.

505 West 10200 South, South Jordan, Utah 84095, USA • 800.552.5512 • Fax: 801.572.0600 • www.ultradent.com

Product Description Similarities:

UltraEZ Desensitizing Gel	Cosmedent Desensitizing Gel	Protect Desensitizing Gel
Composed of potassium nitrate and fluoride ions in a film-like varnish. 3% Potassium Nitrate and 0.11% w/w Fluoride Ion Gel for the treatment of dentin sensitivity.	Composed of potassium nitrate and fluoride ions in a film-like varnish. 3% Potassium Nitrate and 1200 ppm Fluoride Ion Gel for the treatment of dentin sensitivity.	Composed of potassium and fluoride ions in a film-like varnish. Ingredients: Ethanol, water, hydroxypropylcellulose, potassium fluoride, polyethylene glycol, dimethacrylate, methacrylates.
For professional dental use.	For professional dental use.	For professional dental use.
Immediate physical blockage of dentinal tubules to eliminate painful sensitivity.	Immediate physical blockage of dentinal tubules to eliminate painful sensitivity.	Immediate physical blockage of dentinal tubules to eliminate painful sensitivity.

Product Description Differences:

UltraEZ Desensitizing Gel	Cosmedent Desensitizing Gel	Protect Desensitizing Gel
Designed to be used in a custom-fabricated dental tray.	Designed to be tray delivered or may be brushed directly on the affected area.	Designed to be brushed directly on the affected area.

CONCLUSION:

Ultradent deems the UltraEZ Desensitizing Gel to be substantially equivalent and equally safe and effective as that of the predicates: Cosmedent's Tooth Desensitizer and Sunstar Butler's Protect Tooth Desensitizer per comparison noted above.

Tammy Lavery

Aug 7, 2006
Date

Tammy Lavery
Regulatory Affairs Senior Manager
Submitter and Contact
800 552-5512 extension 4323
or direct 801 553-4323
fax 801 553-4609 or 801 572-0600
email: ltamara@ultradent.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JUN 12 2007

Re: K061438
Trade/Device Name: UltraEZ Desensitizing Gel
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: June 8, 2007
Received: June 11, 2007

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.

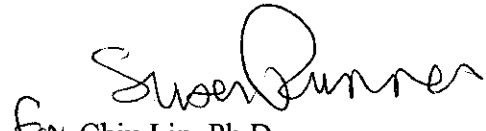
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for 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): Unknown

Device Name: UltraEZ Desensitizing Gel

Indications for use:

The UltraEZ Desensitizing Gel provides a film-like varnish for sensitive teeth, sealing dentinal tubules of over exposed dentin and other exposed areas where post-operative or other dentin sensitivity is a concern. The product is used either by a dental professional in the dental office or provided to the patient for home treatment of dentin sensitivity.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Sign-Off)
of Anesthesiology, General Hospital,
Control, Dental Devices
Number: K061438