K132109

Section 7: 510(k) Summary

This summary of the 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. Applicant's Name and Address

NOV 0 1 2013

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Karen Kakunes, RN
Title:	Sr. Regulatory Affairs Associate
Telephone:	800-552-5512 x4366, 801-553-4366
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Date Summary Prepared:	28 June 2013

II. Name of the Device

Trade Name:	Enamelast™
Common Name:	Cavity Varnish
Device Classification:	Class II
Classification Product Code:	LBH
Regulation No.	CFR 872.3260

III. Device Description:

Enamelast Fluoride Varnish is a flavored, xylitol-sweetened 5% sodium fluoride in a resin carrier delivered in a 0.4mL unit dose blister pack or in a 1.2mL syringe. Applicator brushes are provided with the 0.4mL unit dose blister. Delivery mechanisms are recommended in the instructions for use.

IV. Statement of intended use:

Enamelast™Fluoride Varnish is 5% sodium fluoride in a varnish carrier which produces a mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.

V. Comparison of technological characteristics

Table 7-1: Substantial equivalence comparison

Characteristic	Comparison Product (Flor-Opal Varnish White K080249)	Enamelast™
Intended Use	Flor-Opal Varnish White is 5% sodium fluoride in a varnish carrier which produces a mechanical/chemical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.	Enamelast™ Fluoride Varnish is 5% sodium fluoride in a varnish carrier which produces a mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.
Intended user	Dental professional	Dental professional
Chemical Characteristics	5% sodium fluoride Resin based	5% sodium fluoride Resin based
Delivery system	Syringe-to-syringe mixing system with applicator tip	1.2 mL pre-filled syringe ; 0.4mL unit dose blister pack with applicator brush
Physical properties	**Appearance:** White resinous material **Odor:** Bubble gum or Mint **pH:** Mint – 2.95 **Shelf Life:** 18 months	**Appearance:** A white resinous material **Odor:** Mint or Walterberry (strawberry/amaretto) **pH:** Mint – 3.9; Walterberry – 3.9 **Shelf Life:** 24 months
Biocompatibility	Cytotoxicity	Cytotoxicity Oral Mucosa Irritation Genotoxicity Sensitization
Functional Testing	Film Thickness	Fluoride uptake Fluoride varnish retention Film Thickness

Enamelast is a similar material used in the same way by the same types of users as the identified predicate device Flor-Opal Varnish White, introducing no new major safety or efficacy questions.

Biocompatibility testing shows that the product is safe when used as instructed by a dental professional. In-house comparison testing has been performed on Enamelast, the predicate device, Flor-Opal Varnish White and OT Varnish 5% NaF. The data supports the functionality of Enamelast.

In summary, this submission demonstrates that Enamelast is substantially equivalent in safety and effectiveness and performs equivalently or better to the identified predicate and comparable product for its intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 1, 2013

Ultradent Products, Incorporated
Ms. Karen Kakunes
Senior Regulatory Affairs Associate
505 West 10200 South
South Jordan, UT 84095

Re: K132109
Trade/Device Name: Enamelast™
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: July 17, 2013
Received: July 24, 2013

Dear Ms Kakunes:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6: Statement of Indications for Use

510(k) Number (if known): K132109

Device Name: Enamelast™

Indications for Use: Enamelast™ Fluoride Varnish is 5% sodium fluoride in a varnish carrier which produces a mechanical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.11.12 14:45:06 -05'00'

(Posted November 13, 2003)