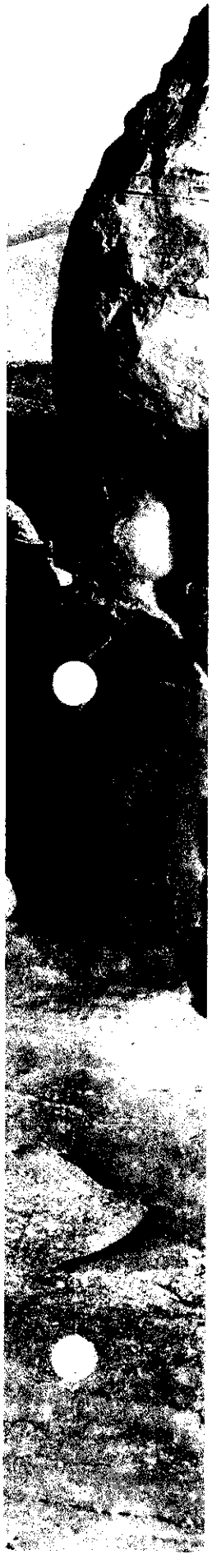
K080249

SPECIAL 510(K) SUMMARY



Flor-Opal Varnish White

This summary of the Traditional 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for Flor-Opal Varnish White

Applicant's Name and Address

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

FEB - 8 ...

Contact Person:	Diane Rogers
Title:	Regulatory Affairs Product Specialist
Telephone:	800-552-5512 x4491, 801-553-4491
FAX:	801-553-4609
Date Summary Prepared:	January 23, 2008

Name of the Device

Trade Name:	Flor-Opal Varnish White
Common Name:	Cavity Varnish
Device Classification:	II
Classification Product Code:	LBH

Legally Marketed Predicate Devices to Which Equivalence is Claimed

The predicate device is Flor-Opal Varnish (K051750) This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description: Flor-Opal Varnish White is a flavored, xylitol-sweetened 5% sodium fluoride in a resin carrier, delivered in a .5ml unit-dose syringe-to-syringe mixing system.

Indications for Use: Flor-Opal Varnish White is a 5% sodium fluoride in a varnish carrier which produces a mechanical/chemical occlusion of the dentinal tubules in the treatment of tooth hypersensitivity.

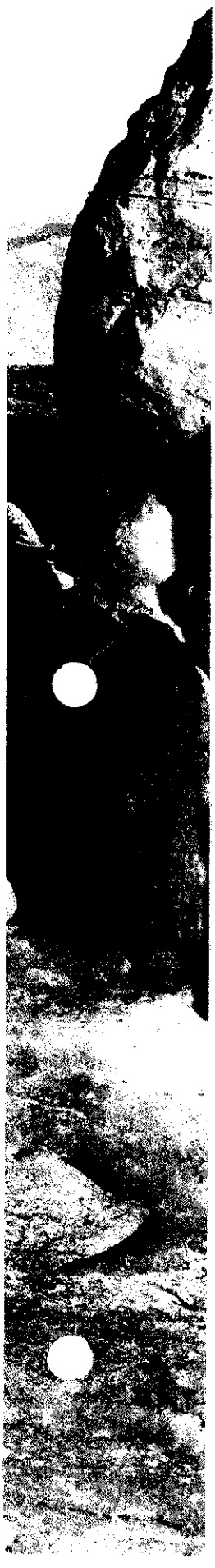


Table 1: Product Comparison

Property	Predicate: Flor-Opal Varnish (K051750)	Flor-Opal Varnish White
Intended Use	Cavity Varnish	Same
Type of material	Resin based	Same
Characteristics	Yellow-white color	White
Human factors	Syringe-to syringe mixing system	Same
Biocompatibility/Safety	Cytotoxicity testing passed. Literature and testing to demonstrate product is safe when used as directed	Same

Technological Characteristics

A pleasantly flavored 5% neutral sodium fluoride in a varnish carrier for relief in dental hypersensitivity. 1ml of varnish contains 50mg of sodium fluoride in an alcohol and natural resin suspension. The varnish adheres well to a wet or dry tooth surface and is white in color when dry. It tolerates saliva, and food while occluding the dentinal tubules.

Brief Description of Testing Performed

Each lot of product must pass internal test specifications prior to release. The results of biocompatibility testing demonstrate that Flor-Opal Varnish WHITE is safe and effective when used according to the Instructions for Use.

Conclusion and Substantial Equivalence

In conclusion, Flor-Opal Varnish WHITE, to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, is substantially equivalent to the Flor-Opal Varnish (K051750), also manufactured by Ultradent Products, Inc. The two products are composed of nearly the same materials, have the same intended use and technological characteristics, and both are safe and effective when used for the indications described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Ms. Diane Rogers
Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

Re: K080249
Trade/Device Name: Flor-Opal Varnish White
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 31, 2008
Received: February 4, 2008

Dear Ms. Rogers:

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.

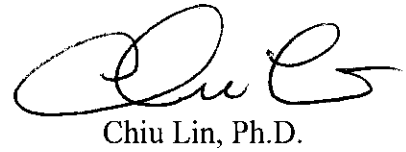
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Statement of Indications for Use

510(k) Number (if known): K080249

Device Name: Flor-Opal Varnish White

Indications for 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.

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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080249

(Posted November 13, 2003)