K122331

OCT 15 2012

SECTION 5

510(k) SUMMARY
for
5% Sodium Fluoride Varnish

1.0 Submitter Information

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
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Date Prepared: September 20, 2012

2.0 Device Name

Proprietary Name:	5% Sodium Fluoride Varnish
Common Name:	Fluoride Varnish
Classification Name:	Cavity Varnish
CFR Number:	872.3260
Device Class:	II
Product Code:	LBH

3.0 Predicate Device

Fluoride Varnish (K031932)
Indications for Use

- Treatment of hypersensitive teeth
- Sealing of dentinal tubules for cavity preparations or on sensitive root surfaces
- Cavity liner

4.0 Description of Device

5% Sodium Fluoride Varnish is a fluoride varnish which is applied to tooth surfaces for sealing dentinal tubules and treatment of hypersensitive teeth. The varnish is applied in a thin layer over the tooth with an applicator brush, and moisture from saliva cures the varnish for adhesion to the tooth surface.

5.0 Indications for Use

5% Sodium Fluoride Varnish is indicated for sealing of dentinal tubules for the treatment of hypersensitive teeth, sensitive root surfaces and for cavity preparations.

6.0 Identification of Risk Analysis Method

Risk analysis was performed on 5% Sodium Fluoride Varnish utilizing a process based on ISO 14971:2007. The results of the risk analysis performed on 5% Sodium Fluoride Varnish concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, performance testing and biocompatibility testing were performed to mitigate other potential risks.

7.0 Description of Safety and Substantial Equivalence

7.1 Technological Characteristics

The technological characteristics of 5% Sodium Fluoride Varnish are very similar to the predicate Fluoride Varnish (K031932). Both varnishes are viscous solutions containing releasable fluoride in rosin bases dissolved by a solvent. 5% Sodium Fluoride Varnish and the predicate Fluoride Varnish (K031932) can both be applied to a wet tooth, and upon contact with saliva, adhere to the tooth surfaces. The film that the varnishes create on the tooth surfaces acts to occlude dentin tubules, which supports relief of hypersensitivity.

7.2 Non-Clinical Performance Data

Non-clinical performance data included testing for tubule occlusion, viscosity, retention on the tooth surface, fluoride release and fluoride content. Stability testing and biocompatibility testing were also performed. The data analyzed in the various tests substantiate that 5% Sodium Fluoride Varnish is as safe and effective as the predicate Fluoride Varnish (K031932).

Biocompatibility testing was performed according to ISO 10993-1:2009. The 5 % Sodium Fluoride Varnish was determined to be non-sensitizing and non-irritating with respect to the requirements for Sensitization and Oral Mucosa Irritation and was determined to be equivalent to legally marketed varnish devices with respect to Cytotoxicity.

7.3 Clinical Performance Data

Due to the low risk nature of 5% Sodium Fluoride Varnish and its commonality of materials used in the dental industry, clinical performance data was not applicable for verification of safety and efficacy. Tubule occlusion efficacy was substantiated by in vitro bench testing.

7.4 Conclusion as to Substantial Equivalence

5% Sodium Fluoride Varnish has been tested for its ability to occlude dentin tubules, retention on tooth surfaces, fluoride release and content, stability and safety. The results of the comparison of the 5% Sodium Fluoride Varnish with respect to intended use, indications for use, and formulation design to the predicate Fluoride Varnish (K031932), as well as the results of the non-clinical testing conducted to assess its performance and biological safety support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

OCT 15 2012

Dentsply International, Incorporated
Ms. Helen Lewis
Director, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17404

Re: K122331
Trade/Device Name: 5% Sodium Fluoride Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 1, 2012
Received: August 2, 2012

Dear Ms. Lewis:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122331

Device Name: 5% Sodium Fluoride Varnish

Indications for Use:

5% Sodium Fluoride Varnish is indicated for sealing of dentinal tubules for the treatment of hypersensitive teeth, sensitive root surfaces and for cavity preparations.

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

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

510(k) Number: K122331