



Food and Drug Administration
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September 18, 2015

3M Company
Shari Myszka, R.Ph., Pharm.D.
Regulatory Affairs Specialist
2510 Conway Avenue
St. Paul, Minnesota 55144-1000

Re: K151302

Trade/Device Name: Clinpro™ Varnish
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: August 10, 2015
Received: August 12, 2015

Dear Dr. Myszka:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
K151302

Device Name
Clinpro™ Varnish

Indications for Use (Describe)

Clinpro™ Varnish is a fluoride, calcium and phosphate containing coating for use in:

- Treating hypersensitive teeth
- Treating exposed dentin and root sensitivity

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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3. 510(k) Summary

3M ESPE Dental

2510 Conway Avenue
St. Paul, MN 55144-1000**510(k) Summary**

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

510(k) Submitter..... 3M ESPE Dental
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

Contact..... Shari L. Myszka, R.Ph., Pharm.D.
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Submission Date..... May 13, 2015

Device Name..... Clinpro™ Varnish

Classification Name..... Cavity Varnish

Regulation Number..... 21 CFR 872.3260

Product Code..... LBH

Classification Panel..... Dental

Classification..... Medical Device, Class II

Device Identification: Cavity varnish is a device that consists of a compound intended to coat a prepared cavity of a tooth before insertion of restorative materials. The device is intended to prevent penetration of restorative materials, such as amalgam, into the dentinal tissue.

Indications for Use: Clinpro™ Varnish is a fluoride, calcium and phosphate containing coating for use in:

- Treating hypersensitive teeth
- Treating exposed dentin and root sensitivity

Predicate Devices:

Vanish™ 5% Sodium Fluoride White Varnish (K092141)
Puldent® Fluoride Varnish (K093620)
Puldent® Activ Varnish (K112946)
Duraphat® 5% Sodium Fluoride Varnish (K945794)

**Description of Device:**

Clinpro™ Varnish is a fluoride, calcium and phosphate containing coating for use in treating hypersensitive teeth and exposed dentin and root sensitivity. Clinpro™ Varnish is moisture and saliva-activated when applied to enamel and dentin. It will spread on and adhere to moist teeth. Clinpro™ Varnish is an alcohol/water-based solution of dental polymer resins. The product is sweetened with xylitol and sucralose. Clinpro™ Varnish contains two fluoride sources, 3% sodium fluoride and 3% strontium fluoride (equivalent to 2.26% fluoride ion). Clinpro™ Varnish provides both an initial release in the first hour and a continued release during the next 24 hours. Clinpro™ Varnish also contains sources of calcium and phosphate, including functionalized tri-calcium phosphate exclusively from 3M ESPE. Clinpro™ Varnish is supplied in unit-dose packages containing 0.50 ml of varnish coating. Each 0.50 ml of Clinpro™ Varnish contains 13.8 mg sodium fluoride and 13.8 mg strontium fluoride, equivalent to 10.4 mg total fluoride ion.

Technological Characteristics:

The basic composition, fundamental technology and intended use of Clinpro™ Varnish are substantially equivalent to the predicate devices. Clinpro™ Varnish is a fluoride, calcium and phosphate containing coating to provide immediate and sustained relief of dental pain or hypersensitivity. The immediate relief of hypersensitivity is achieved by the hardened resin film that forms immediately after application and occludes the dentin tubules. Clinpro™ Varnish is unique formulation that utilizes novel resin polymer coating technology to incorporate the additional sources of fluoride, calcium and phosphate. *In vitro* fluoride release testing shows that Clinpro™ Varnish provides both an initial release in the first hour and a continued release during the next 24 hours.

The table below summarizes the basic composition, fundamental technology and intended use of Clinpro™ Varnish and the predicate varnishes:

Vanish™ 5% Sodium Fluoride White Varnish	Pulpdent® Fluoride Varnish	Pulpdent® Activ Varnish	Duraphat® 5% Sodium Fluoride Varnish	Clinpro™ Varnish
Primary Predicate	Reference Predicate	Reference Predicate	Reference Predicate	Subject Device
K092141	K093620	K112946	K945794	K151302
Basic Composition				
Rosin Varnish	Rosin Varnish	Rosin Varnish	Rosin Varnish	Polymer Resin Varnish*
Fundamental Technology				
Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion	Dentin Tubule Occlusion
Indication for Use				
Treatment of Hypersensitive Teeth and Exposed Dentin and Root Sensitivity	Treatment of Dental Hypersensitivity	Treatment of Dental Hypersensitivity	Treatment of Dental Hypersensitivity	Treatment of Hypersensitive Teeth and Exposed Dentin and Root Sensitivity

* The polymer resin varnish and the predicate rosin varnishes are film forming materials that block dentin tubules and act as carriers for the fluoride, calcium and phosphate. The synthetic polymer resin was selected due to its lower variability in composition and properties as compared to the naturally-sourced rosins and is substantially equivalent in performance to the rosin varnishes.

Performance Data:

In vitro testing was conducted with Clinpro™ Varnish and the predicate devices, Vanish™ 5% Sodium Fluoride White Varnish, Pulpdent® Active Varnish and Duraphat® 5% Sodium Fluoride Varnish. Properties evaluated include dentin tubule penetration and *in vitro* fluoride, calcium and phosphate release. SEM and optical images show that the devices form a thin film penetrating dentin tubules. *In vitro* fluoride release testing shows that Clinpro™ Varnish provides both an initial release in the first hour and a continued release during the next 24 hours. Clinpro™ Varnish utilizes a resin polymer coating technology to incorporate the additional sources of fluoride, calcium and phosphate as compared to the predicate devices that utilize a rosin polymer coating.

All varnishes function as film forming materials that block dentin tubules for use in treating dental hypersensitivity. Clinpro™ Varnish and Varnish™ Varnish are indicated for use on exposed dentin and root sensitivity for treating dental hypersensitivity as well.

Stability testing was conducted by evaluating the physical properties of the device at various storage conditions to confirm a shelf life at room temperature of 24 months. Biocompatibility testing for the device included cytotoxicity, sensitization, irritation/ intracutaneous reactivity and acute systemic toxicity.



Performance Standards:

Clinpro™ Varnish complies with the following ISO standards:

- ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2009, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-3:2009, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity and Reproductive Toxicity
- ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
- ISO 10993-11:2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ISO 10993-12:2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials
- ISO 7405:2008, Dentistry – Evaluation of Biocompatibility of Medical Devices Used in Dentistry

Substantial Equivalence Statement:

Results of the nonclinical and clinical testing demonstrate that Clinpro™ Varnish is substantially equivalent to the legally marketed predicate devices in terms of intended use, indications for use, basic composition, fundamental technology, delivery presentation, directions for use, physical properties and biocompatibility.