

K090519



APR 15 2009

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

**Submitter**

Company:	3M ESPE Dental Products
Street:	3M Center Bldg 260-2A-17
ZIP-Code, City:	St. Paul, Mn. 55144
Country:	USA
Establishment Registration Number:	2110898
Official Correspondent:	Karen O'Malley Sr. Regulatory Specialist
Phone:	651 736-7326
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Date:	February 20, 2009

**Name of Device**

Proprietary Name:	Vanish Varnish
Classification Name:	Cavity Varnish 21 C.F.R. §872.3260 as a Class II device.
Common Name:	Cavity Varnish

**Predicate Devices**

Device	510(k)
Sci-Pharm DFV Varnish	K982915
Universal Cavity Varnish	K802926
DuraShield Plus	K082198

**Description and Technology Equivalence**

Vanish™ Varnish, 5% Sodium Fluoride Varnish is classified as Cavity Varnish (21 C.F.R. §872.3260) because it is a device that provides relief from tooth surface hypersensitivity when applied to enamel and dentin surfaces by forming a film that facilitates occlusion of compromised surfaces including open dentinal tubules.

Vanish Varnish is a topically applied, flavored cavity varnish containing sodium fluoride in a rosin based preparation. The varnish is an insoluble viscous liquid that forms a film on tooth surfaces. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The chemical composition is identical to predicate fluoride containing rosin based cavity varnish devices that have been in use for decades. The data provided in this 510(k) submission shows that the composition is safe based on the biocompatibility assessment conducted based on ISO10993 and ISO 7405.

This product is equivalent to current varnishes in properties, intended use and composition. Results provided in the submission confirm the equivalent to the predicate devices with common indications.

**Indications for Use:**

Vanish Varnish is for use on sensitive teeth, over exposed dentin and root surface sensitivity and under temporary restoratives and cements where post-operative sensitivity is of concern.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Karen O'Malley, RAC  
3M Company  
Dental Products Division  
3M Center, Building 260-2A-17  
St. Paul, Minnesota 55144-1000

APR 15 2009

Re: K090519  
Trade/Device Name: Vanish™ Varnish  
Regulation Number: 21 CFR 872.3260  
Regulatory Class: II  
Product Code: LBH  
Dated: March 16, 2009  
Received: March 18, 2009

Dear Ms. O'Malley:

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 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.

Page 2- Ms. O'Malley

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

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,



Susan Runner, D.D.S., MA  
Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K090519

## Indications for use

### Indications for Use Statement Indications for Use

510(k) Number (if known): K09

Device Name: Vanish™ Varnish

#### Indications for Use:

- Treatment of hypersensitive teeth
- use on exposed dentin and root sensitivity
- under temporary restoratives and cements where post-operative sensitivity is of concern.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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