SEP 1 5 2003

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

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570 West College Avenue
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P. J. Lehn Telefax (717) 849-4343

K031932

CONTACT: P. Jeffery Lehn

DATE PREPARED: June 19, 2003

TRADE OR PROPRIETARY NAME: FLUORIDE VARNISH

CLASSIFICATION NAME: Cavity Varnish 872.3260

PREDICATE DEVICES: Duraphat Fluoride Varnish K945794
Duragard Fluoride Varnish K002581

DEVICE DESCRIPTION: FLUORIDE VARNISH coats a prepared tooth surface prior to placement of any restorative materials to prevent any of the restorative materials from penetrating into the dentinal tissue. FLUORIDE VARNISH contains releasable fluoride.

FLUORIDE VARNISH will be offered in unit dose vials with applicator brushes. Each vial contains material to treat 4-8 teeth, depending on their size.

INTENDED USE: Intended for: 1) treatment of hypersensitive teeth; 2) sealing the dentinal tubules for cavity preparations or on sensitive root surfaces; and 3) a cavity liner.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in FLUORIDE VARNISH have been used in legally marketed devices or were found safe for dental use.

FLUORIDE VARNISH has been evaluated and passed biocompatibility testing for cytotoxicity, acute oral toxicity, irritation, and sensitization.

We believe that the prior use of the components of FLUORIDE VARNISH in legally marketed predicate devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of FLUORIDE VARNISH for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 5 2003

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K031932
Trade/Device Name: Fluoride Varnish
Regulation Number: 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: June 19, 2003
Received: June 23, 2003

Dear Mr. Lehn:

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.

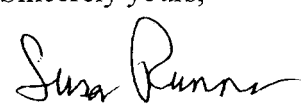
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K031932

Device Name: **FLUORIDE VARNISH**

Indications for Use:

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

Kim Nesbey for MSA

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

510(k) Number: K031932

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)