

NOV 17 1999

**510(k) SUMMARY****DENTSPLY**

NAME &amp; ADDRESS:

**DENTSPLY International**  
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 York, PA 17405-0872  
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K992822

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME: SEAL &amp; PROTECT™ DENTAL VARNISH

CLASSIFICATION NAME: cavity varnish 872.3260

PREDICATE DEVICES: Prime &amp; Bond® NT™ Universal Dental Adhesive K982394

**DEVICE DESCRIPTION:** SEAL & PROTECT™ DENTAL VARNISH is a nanofilled light-curing dental varnish designed to protect exposed dentine areas, both mechanically and by way of an antimicrobial agent.

**INTENDED USE:** SEAL & PROTECT™ DENTAL VARNISH is a protective sealant for exposed dentine. The Indications for Use are: (1) Reduction of abrasion and erosion of exposed cervical dentine; and (2) Treatment of hypersensitive cervical areas.

**TECHNOLOGICAL CHARACTERISTICS:** All of the components found in SEAL & PROTECT™ DENTAL VARNISH have been used in legally marketed devices.

SEAL & PROTECT™ DENTAL VARNISH was evaluated for cytotoxicity (L929) and mutagenicity (Ames Test). The conclusions indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed. The possibility of migration of constituents occurring during the application and polymerization phase cannot be absolutely ruled out. However, in light of the low volume of material applied, the low solubility in physiological liquids and the inert properties of the polymerized synthetic matrix, the amount and type of the substances temporarily released from the product must be considered as harmless.

We believe that the prior use of the components of SEAL & PROTECT™ DENTAL VARNISH in legally marketed devices, the results of biocompatibility testing, and the performance data support the safety and effectiveness of SEAL & PROTECT™ DENTAL VARNISH for the indicated uses.

REVISED November 12, 1999

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 6 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Helen Lewis  
Director, Corporate Compliance and Regulatory Affairs  
DENTSPLY International  
Susquehanna Commerce Center  
221 West Philadelphia Street  
York, Pennsylvania 17405

Re: K992822

Trade/Device Name: Seal & Protect™ Dental Varnish  
Regulation Number: 21 CFR 872.3260  
Regulation Name: Cavity Varnish  
Regulatory Class: II  
Product Code: LBH  
Dated: August 20, 1999  
Received: August 23, 1999

Dear Ms. Lewis:

This letter corrects our substantially equivalent letter of November 17, 1999.

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 (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.

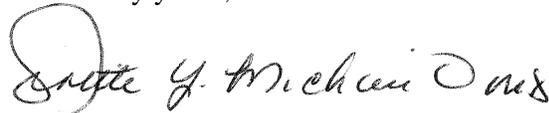
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Chiu S. Lin, PhD  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

(As Required by 21 CFR 801.109)

510(K) Number: K99 2822

Device Name: SEAL & PROTECT™ DENTAL VARNISH

SEAL & PROTECT™ DENTAL VARNISH is a protective sealant for exposed dentine. The

Indications for Use are:

- Reduction of abrasion and erosion of exposed cervical dentine
- Treatment of hypersensitive cervical areas

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over-The-Counter Use