AUG 1 9 2002

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY Internati nal
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 849-4762~~

K021805

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: May 31, 2002

TRADE OR PROPRIETARY NAME: Seal & Protect™ Protective Sealant

CLASSIFICATION NAME: cavity varnish 872.3260

PREDICATE DEVICES: Seal & Protect™ Protective Varnish K992822

DEVICE DESCRIPTION: Seal & Protect™ Protective 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™ Protective 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: Seal & Protect™ Protective Sealant is identical to K992822, with the exception of the addition of a contraindication.

Therefore, we believe that Seal & Protect™ Protective Sealant is safe and effective for the unchanged indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 9 2002

Mr. P. Jeffery Lehn
Director, Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K021805
Trade/Device Name: Seal & Protect™ Protective Sealant
Regulation Number: 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: May 31, 2002
Received: June 3, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

for Timothy A. Ulatowski
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): K021805

Device Name: **SEAL & PROTECT™ PROTECTIVE SEALANT**

Seal & Protect™ Protective Sealant 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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

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

for Dr. Susan Runner

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

510(k) Number: K021805