510(k) SUMMARY

DENTSPLY

K992519

OCT 22 1999

NAME & ADDRESS: **DENTSPLY International**
570 West College Avenue
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York, PA 17405-0872
(717) 845-7511
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P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME: NRC™ NON-RINSE CONDITIONER

COMMON OR USUAL NAME: Tooth conditioner

CLASSIFICATION NAME: Conditioner, pit and fissure sealant and 872.3765

PREDICATE DEVICE: Caulk® Tooth Conditioner Liquid Pre-1976 Device

DEVICE DESCRIPTION: NRC™ NON-RINSE CONDITIONER is a no-rinse etching/ conditioning solution for use on enamel with selected adhesive and preventive dental materials.

NRC™ NON-RINSE CONDITIONER partially dissolves the minerals within the enamel. This partial dissolution results in increased surface area due to micro-porosities created in the affected substrates. This allows for more intimate contact and penetration of the sealant material with the tooth, increasing the potential for adhesion of the sealant. To aid in the adhesion, an adhesive bonding agent is applied to the acid treated surfaces.

INTENDED USE: Used to clean instrumented enamel prior to the application of selected dental adhesive and preventive dental materials.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in NRC™ NON-RINSE CONDITIONER have been used in legally marketed devices.

NRC™ NON-RINSE CONDITIONER was evaluated by the Ames Mutagenicity Test and found to be non-mutagenic.

We believe that the prior use of the components of NRC™ NON-RINSE CONDITIONER in legally marketed devices, the biocompatibility testing, and the performance data provided support the safety and effectiveness of NRC™ NON-RINSE CONDITIONER for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1999

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

Re: K992519
Trade Name: NRC™ Non-Rinse Conditioner
Regulatory Class: II
Product Code: EBC
Dated: July 27 1999
Received: July 28, 1999

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital 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: K992519

Device Name: NRC™ NON-RINSE CONDITIONER

Used to clean instrumented enamel prior to restoration of tooth structure with selected dental adhesive and preventive dental materials.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992519