510(k) SUMMARY

DENTSPLY

K972234

JUN 30 1997

NAME & ADDRESS:

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: June 12, 1997

TRADE OR PROPRIETARY NAME: RCT GEL™

CLASSIFICATION NAME: Dental Instrument 872.4565

PREDICATE DEVICE: RC Prep Pre-1976 Device

DEVICE DESCRIPTION: RCT GEL™ allows for cleansing action that facilitates easy removal of vital pulp tissue and necrotic pulp tissue from the root canal. It is designed to be used with endodontic irrigation with sodium hypochlorite solutions. Oxygen bubbling occurs through the release of oxygen from the carbamide peroxide. This action allows for pulp tissue, dentinal shavings and debris to float out.

The physical properties of RCT GEL™ and the predicate device are similar, i.e., pH values, viscosity, appearance, color, and odor.

INTENDED USE: RCT GEL™ is used in the chemical and mechanical cleansing of the root canal preparation during endodontic therapy.

TECHNOLOGICAL CHARACTERISTICS: All components in RCT GEL™ have been used in predicate medical devices or have been found safe for dental use.

We believe that, due to the long established safe and efficacious use of the predicate device in the same intended use, the identical concentrations of active ingredients, the short duration of contact within the oral cavity, and the decomposition and thorough removal of the product from the canal space, the use of RCT GEL™ does not require additional biocompatibility testing and that the GEL is safe and effective for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1997

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

Re: K972234
Trade Name: RCT Gel™ Root Canal Therapy Gel
Regulatory Class: I
Product Code: EIC
Dated: June 12, 1997
Received: June 16, 1997

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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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,

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: K972234

Device Name: RCT GEL™ ROOT THERAPY GEL

Indications for Use:

Used in the chemical and mechanical cleansing of the root canal preparation during endodontic therapy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972234

Prescription Use ✓ OR Over-The-Counter Use ____