510(k) SUMMARY K032361

DENTSPLY

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JAN 12 2004

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: JUL 30 2003

TRADE OR PROPRIETARY NAME: EndoPure™ Root Canal Cleanser

CLASSIFICATION NAME: Root Canal Cleanser (unclassified)

PREDICATE DEVICES: EDTA Root Canal Cleanser K003422

DEVICE DESCRIPTION: EndoPure™ Root Canal Cleanser is a two-part liquid/powder formulation. The mixed solution cleanses the root canal, removes the smear layer, and kills the bacteria in an instrumented root canal without harming the tooth structure or soft tissue.

The EndoPure™ Root Canal Cleanser is easily dispensed using a disposable syringe.

INTENDED USE: EndoPure™ Root Canal Cleanser is used to chemically clean and disinfect a root canal system after endodontic instrumentation.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in EndoPure™ Root Canal Cleanser been used in legally marketed devices.

EndoPure™ Root Canal Cleanser has been evaluated for cytotoxicity and mutagenicity and found to be non-cytotoxic and non-mutagenic.

We believe that the prior use of the components of EndoPure™ Root Canal Cleanser in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of EndoPure™ Root Canal Cleanser for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2004

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: K032361
Trade/Device Name: EndoPure™ Root Canal Cleanser
Regulation Number: N/A
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: December 23, 2003
Received: December 24, 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.

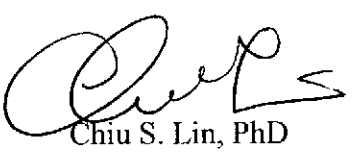
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Indications for Use

510(k) Number (if known): K032361

Device Name: EndoPure™ Root Canal Cleanser

Indications for Use:

Used to chemically clean and disinfect a root canal system after endodontic instrumentation

Contraindication:

EndoPure™ is contraindicated for persons who have shown hypersensitivity to doxycycline or any other tetracyclines.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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