510(k) Summary for EPIEN ROOT CANAL CLEANSER

FEB 0 1 2013

Submitter/Holder	EPIEN Medical, Inc. 4225 White Bear Parkway Suite 600 St. Paul, MN 55110-3389
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Date Prepared	November 13, 2012
Trade Name	EPIEN ROOT CANAL CLEANSER
Common Name	Tooth Root Canal Cleanser
Classification Name	Root Canal Cleanser, Unclassified
Predicate Devices	• K063703, Ultradent Products Ultradent Citric Acid 20% Solution • K053167, DENTSPLY International Biopure™ MTAD™ Root Canal Cleanser • K061689, PuriCore, Inc Aquatine™ EC Endodontic Cleanser
Device Description	EPIEN ROOT CANAL CLEANSER is an aqueous, moderately viscous and dense solution that is used to irrigate root canals to provide a rinse to tooth surfaces as an adjunctive to professional mechanical dental procedures. The EPIEN ROOT CANAL CLEANSER is applied onto tooth root canal surfaces for a brief duration using standard dental irrigation syringes. It is then rinsed away with saline or water. EPIEN ROOT CANAL CLEANSER cleanses the root canal system by enhancing the removal of the post-instrumentation smear layer. The EPIEN ROOT CANAL CLEANSER consists of hydroxybenzenesulfonic acid, hydroxymethoxybenzenesulfonic acid, sulfuric acid, and water, in addition to a colorant.
Intended Use	EPIEN ROOT CANAL CLEANSER is indicated for use as an adjunctive rinse of tooth root canal systems and adjacent tooth surfaces during standard professional dental procedures to enhance the removal of post-instrumentation dentinal debris and smear-layer within the root canal systems.
Characteristics	EPIEN ROOT CANAL CLEANSER improves the thoroughness of mechanical cleaning procedures by providing a mechanical rinsing action to the surfaces of the tooth root. EPIEN ROOT CANAL CLEANSER also provides superficial dehydration of material in instrumented tooth root canal systems on contact. This causes reduction of the attachment of dentinal debris and the smear layer to tooth surfaces. This disruption assists with the removal of the smear layer.
Performance Data	The performance data provided support the safety and effectiveness of the EPIEN ROOT CANAL CLEANSER for the proposed intended use. EPIEN conducted bench and animal studies to assess the

	mechanical rinsing action of the product and desiccation effects. The studies demonstrate that the product is safe and effective for its intended use. Biocompatibility studies indicate that the product is non-toxic, non-sensitizing, a non-irritant, and non-mutagenic. The following studies were conducted: • 36-month real-time stability/shelf-life studies • Biocompatibility studies in accordance with ISO 10993-1 (cytotoxicity, sensitization, mutagenicity, irritation, and intracutaneous reactivity) • Chemical and physical characterization studies (Chromatographic Analyses, Acid Titration Curve/Total Acidity, Viscosity, Hygroscopicity, Exothermia on Solvation, Enamel and Dentin Erosion Assays) • In vitro microbial biofilm disruption assays (Disclosing Solution Demonstration, MBEC Assays, Dental root canal and root surface rinse test) • Animal Performance Testing (Canine Oral Mucosa Metabolism and IV ADME of c14-ERCC, Canine Vital Pulp ERCC Exposure Study, and Canine Periodontal tissue ERCC Exposure Study)
Predicates Comparison	The proposed device is substantially equivalent to the currently cleared and marketed devices. The EPIEN ROOT CANAL CLEANSER is equivalent in intended use, design characteristics, and method of application to predicate devices. The composition of the EPIEN ROOT CANAL CLEANSER represents a different technology from the predicates in that it is composed of an aqueous solution of sulfonated aromatics and free sulfuric acid. The questions of safety and effectiveness that have applied to the predicates also apply to the EPIEN ROOT CANAL CLEANSER in an identical manner. The results from biocompatibility, bench, and animal studies demonstrate that any differences between the EPIEN ROOT CANAL CLEANSER and the predicate devices do not constitute a new intended use, affect safety or effectiveness, or raise different questions of safety and effectiveness. The information submitted in this 510(k) support a determination of Substantial Equivalence for the EPIEN ROOT CANAL CLEANSER product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 1, 2013

Epien Medical, Incorporated
C/O Mr. Jeffery K. Shapiro
Director
Hyman Phelps & McNamara. P.C.
700 Thirteenth Street, North West, Suite 200
WASHINGTON DC 20005

Re: K123538
Trade/Device Name: Epien Root Canal Cleanser
Regulation Number: Unclassified
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: November 16, 2012
Received: November 16, 2012

Dear Mr. Shapiro:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123538

Device Name: EPIEN ROOT CANAL CLEANSER

Indications for Use: EPIEN ROOT CANAL CLEANSER is indicated for use as an adjunctive rinse of tooth root canal systems and adjacent tooth surfaces during standard professional dental procedures to enhance the removal of post-instrumentation dentinal debris and smear-layer within the root canal systems.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen
2013.02.01 10:09:42 -05'00'

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

510(k) Number: _____