K061689

AUG 24 2006

510(k) SUMMARY OF AQUATINE™ EC ENDODONTIC CLEANSER

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R §807.92.
Submitter	PuriCore, Inc. 320 King of Prussia Road Radnor, PA 19087
Contact Person	Howard Mann 320 King of Prussia Road Radnor, PA 19087 484-321-2703 610-341-0503 fax
Date Prepared	August 8th, 2006
Trade Name	**Aquatine™ EC**
Common Name	Endodontic Cleanser
Classification Name	Cleanser, Root Canal
Predicate Devices	Pulpdent Sodium Hypochlorite Solution.; Pulpdent Corp., K962743, August 6th, 1996, Oxy-Glide Root Canal Cleanser & Lub.; Super Glide Inc., K992919, Nov. 19th, 1999 and Biopure MTAD Root Canal Cleanser Dentsply Intl., Inc., K053167, December 8th, 2005.
Description	**Aquatine™ EC** Endodontic Cleanser irrigates, cleanses and debrides. The mechanical action of the solution moving in the root canal facilitates easy removal of debris and necrotic pulp tissue from the root canal.
Indications for Use	**Aquatine™ EC** Endodontic Cleanser is intended to irrigate, cleanse, and debride root canal systems.
Substantial Equivalence	The product is similar in function and intended use to: • Pulpdent Sodium Hypochlorite Solution, manufactured by Pulpdent Corp. • Oxy-Glide Root Canal Cleanser & Lub. manufactured by Super Glide Inc., that includes among its labeled uses the chemical and mechanical cleansing of root canal preparation during endodontic therapy. • Biopure MTAD and Endopure Root Canal Cleansers manufactured by Dentsply Intl., Inc., that include among their labeled uses cleaning the canal and disinfecting the root canal system after endodontic instrumentation.
Non-clinical Performance	The performance and biocompatibility data provided support the safety and effectiveness of **Aquatine™ EC** Endodontic Cleanser for the indicated uses. All components found in **Aquatine™ EC** Endodontic Cleanser have been used in legally marketed devices
Conclusion	**Aquatine™ EC** Endodontic Cleanser is substantially equivalent to the currently cleared and marketed Pulpdent Sodium Hypochlorite Solution, Oxy-Glide Root Canal Cleanser & Lub, Endopure Root Canal Cleanser and Biopure MTAD Root Canal Cleanser.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 2006

Mr. Howard K. Mann
Vice President
PuriCore, Incorporated
320 King of Prussia Road, Suite 200
Radnor, Pennsylvania 19087

Re: K061689
Trade/Device Name: Aquatine™ EC Endodontic Cleanser
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: KJJ
Dated: August 10, 2006
Received: August 11, 2006

Dear Mr. Mann:

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 (240) 276-0115. 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 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061689

Indications for Use

510(k) Number (if known): K061689

Device Name: Aquatine™ EC Endodontic Cleanser
Indications for Use:

Aquatine™ EC Endodontic Cleanser is intended to irrigate, cleanse and debride root canal systems.

Sign-Off)
ion of Anesthesiology, General Hospital,
ion Control, Dental Devices
Number: K061689

Prescription Use ___X___ **OR** **Over-The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)