K063703

SPECIAL 510(k) PREMARKET SUMMARY

Ultradent Citric Acid 20% Solution

DEC 2 1 2006

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for Citric Acid 20% Solution.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

Contact Person:	Corey Jaseph
Title:	Regulatory Affairs Product Specialist
Telephone:	800-552-5512 x4586, 801-553-4586
FAX:	801-553-4609
Date Summary Prepared:	December 11, 2006

Name of the Device

Trade Name:	Citric Acid 20% Solution
Common Name:	Cleanser, Root Canal
Risk Classification:	Unclassified (pre-amendment)
Classification Product Code:	KJJ

Legally Marketed Predicate Devices to Which Equivalence is Claimed:

Predicate: Citric Acid 10% Solution, Ultradent Products, Inc. (K032627). Manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, UT 84095.

Product Description and Intended Use:

Citric Acid 20% is a slightly thickened, water-soluble solution. It is slightly orange-tinted for easy identification and is provided in a 30 ml IndiSpense® Syringe. Citric Acid facilitates removal of calcium hydroxide materials (e.g., UltraCal®) from canal walls. It can also be used as a mild etchant/conditioner for smear layer removal. Ultradent's EDTA 18%, a chelating agent, is an alternative for this purpose. Regardless of regimen used, we recommend a final rinse with clean, bacteria-free water, plain EDTA or local anesthetic.

Table 1: Product Comparison Table

Property	Citric Acid 20% Solution	Citric Acid 10% Solution
Intended Use	Facilitates removal of calcium hydroxide from canal walls, and functions as a mild etchant/conditioner for smear layer removal.	Same
Active Ingredient	Citric acid	Same
Biocompatibility/Safety	Clinical literature demonstrates that citric acid is safe and non-cytotoxic (see Section VII)	Same
Properties	Orange-tinted, slightly thickened	Same
How Supplied	30 mL IndiSpense® Syringe	Same

Technological Characteristics

Citric acid has been used as an irrigant during root canal procedures for many years. One of its attractive features is its non-cytotoxicity, while still being effective in removing calcium hydroxide and the smear layer caused by instrumentation. Many different concentrations of citric acid have been used, with varying degrees of success. Both 10 and 20% solutions are used successfully for these purposes (see Section VII, Literature Review).

Brief Description of Testing Performed and Conclusion

A scanning electron microscope study was performed to evaluate the ability of EDTA, 10% citric acid and 20% citric acid in cleaning, chelating and exposing dentinal tubules. The results showed that more dwelling time allowed the irrigants to function more effectively in cleaning and exposing dentinal tubules. It appeared that 20% citric acid and EDTA were slightly more effective than 10% citric acid; however, these differences did not appear to be significant.

Substantial Equivalence

In conclusion, Citric Acid 20% Solution, to be manufactured and marketed by Ultradent Products, Inc., 505 West 10200 South, South Jordan, UT 84095, is substantially equivalent to Citric Acid 10% Solution, also manufactured by Ultradent Products, Inc. The two products are composed of the same materials, have the same intended use and both are safe and effective for use for the indications described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Corey Jaseph
Regulatory Affairs Product Specialist
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

DEC 21 2006

Re: K063703
Trade/Device Name: Ultradent Citric Acid 20% Solution
Regulation Number: N/A
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: December 11, 2006
Received: December 13, 2006

Dear Ms. Jaseph:

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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K063703

Device Name: Ultradent Citric Acid 20% Solution

Indications for Use:

Citric Acid 20%, a root canal cleanser, is intended to etch root canal walls just prior to obturation to allow an optimum seal.

Prescription Use X (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)

Susan Runner

Division of Ophthalmic, General Hospital, Infection Control, and Dental Devices

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(Posted November 13, 2003)