



Ultradent Products, Inc.  
Corey Jaseph  
Regulatory Affairs Manager  
505 W Ultradent Drive (10200 South)  
South Jordan, Utah 84095

February 9, 2018

Re: K173163  
Trade/Device Name: ChlorCid, ChlorCid V, ChlorCid Surf  
Regulatory Class: Unclassified  
Product Code: KJJ  
Dated: January 9, 2018  
Received: January 11, 2018

Dear Corey 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. 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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

Tina Kiang, Ph.D.  
Acting Director  
Division of Anesthesiology,  
General Hospital, Respiratory,  
Infection Control, and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug AdministrationSouth Jordan, UT 84095  
Form Approved OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

**K173163**

Device Name

ChlorCid family - ChlorCid, ChlorCid V, ChlorCid Surf

Indications for Use (Describe)

ChlorCid, ChlorCid V and ChlorCid Surf are used for irrigating, cleaning, instrumentation and debriding of root canal preparations.

Type of Use (Select one or both, as applicable)

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## Traditional 510(k) Summary

This summary of substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92 for the ChlorCid® family of products.

### I. Applicant's Name and Address

Ultradent Product, Inc.  
505 West Ultradent Drive (10200 South)  
South Jordan, UT 84095

Contact Person: Ms. Corey Jaseph, MS, RAC  
Title: Regulatory Affairs Manager  
Telephone: 800-553-4420  
Fax: 801-553-4609

Date Summary Prepared: February 5, 2018

### II. Name of the Device

Trade Name: ChlorCid, ChlorCid V, ChlorCid Surf  
Common Name: Cleanser, Root Canal  
Device Classification: Unclassified  
Classification Product Code: KJJ  
Regulation Number: Pre-amendment device

### III. Device Description

The ChlorCid family of products are aqueous solutions of 3% sodium hypochlorite used for endodontic procedures. When desired, ChlorCid V is a more viscous solution for enhanced flow control and lubrication, and ChlorCid Surf includes a surfactant which assists in the product's ability to penetrate in tight canal spaces.

### IV. Indications for Use

ChlorCid, ChlorCid V and ChlorCid Surf are used for irrigating, cleaning, instrumentation and debriding of root canal preparations.

### V. Predicate Device

The predicate devices, ChlorXtra and 3% NaOCL, are cleared under 510(k) K082470 and are legally manufactured and distributed by Inter-Med, Inc and Vista-Dental, Inc.; 2200 Northwestern Ave, Racine, WI 53404.

## VII. Comparison of Technological Characteristics

### Predicate technological comparison:

The technology, delivery, and intended use of the ChlorCid family of products are substantially equivalent to the identified predicates as outlined in Table 12-1:

	Ultradent 510(k) Submission			Predicate Device: K082470	
	ChlorCid	ChlorCid V	ChlorCid S	Vista 3% NaOCL	Vista ChlorXtra
<b>Indications for Use</b>	ChlorCid, ChlorCid V and ChlorCid Sur are used for irrigating, cleaning, instrumentation, and debriding of root canal preparations.			Sodium hypochlorite 3% & 6% solution and Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-Xtra are solutions used for the debridement and in the instrumentation of root canal. Sodium hypochlorite 3% & 6% and Chlor-Xtra are sodium hypochlorite solutions in water.	
<b>Sodium Hypochlorite Concentration</b>	3%	3%	3%	3%	6%
<b>Surfactant</b>	None	None	Sodium alkanoate (compatible with chlorine, biodegradable)	None	Triton X-100
<b>Containers</b>	30 mL container used with disposable syringes, 16 oz bottle	30 mL container used with disposable syringes	30 mL container used with disposable syringes, 16 oz bottle	3 and 5 mL pre-filled syringes, 16 oz bottle	3 and 5 mL pre-filled syringes, 16 oz bottle
<b>pH</b>	11.8	12.7	12.2	11.5	12.7
<b>Contact Angle (wettability)</b>	26.6 ± 0.4	Analysis Not Done	20.3 ± 0.7	Analysis Not Done	22.5 ± 2.4
<b>Viscosity (cP)</b>	13.5	96.8	16.1	Not done	Not done
<b>Biocompatibility</b>	Literature	Literature	Literature	Literature	Literature

The ChlorCid family of products are substantially equivalent to the identified predicate with respect to intended use, sodium hypochlorite concentration, presence of a surface acting agent (surfactant), pH, and biocompatibility. Although the indications for use statement are not

exactly the same, as the predicate discusses the composition and the ChlorCid family does not, in fact, the composition is substantially similar including the use of a surface-active agent in one product variation. Finally, the uses of the predicate and ChlorCid products are the same, for debriding and irrigating root canals.

Testing to demonstrate equivalence with the predicate included a sodium hypochlorite assay, pH, viscosity, and contact angle (measure of wettability; used on the surfactant-containing solutions). These tests show that ChlorCid, ChlorCid V, and ChlorCid Surf have the same concentration of sodium hypochlorite, the same pH, and include a similar surfactant for the same reason (wettability/penetrability). ChlorCid V also contains a small amount of thickener (<2% w/w) to slightly increase viscosity over ChlorCid and ChlorCid Surf for enhanced lubrication and flow control. ChlorCid V's viscosity has been evaluated against ChlorCid, and a reference device used for a similar purpose, File-Eze (KJJ, K060335). Flow control has been demonstrated in a simulated root canal, showing the ChlorCid V stays where placed, whereas ChlorCid immediately flows to the bottom of the canal. Lubrication was demonstrated in a simulated canal, showing that ChlorCid V allows a safety torque motor to continue to rotate in order to complete instrumentation, whereas ChlorCid used in the same manner causes the safety torque motor to hit its maximum torque and stop prior to completing instrumentation. In addition, packaging and stability studies show that ChlorCid, ChlorCid V, and ChlorCid Surf in their primary containers maintain an acceptable concentration of sodium hypochlorite over the recommended shelf life, and the packaging is protective of the product during shipping and handling. Finally, a simulated irrigation protocol on extracted molars demonstrates that ChlorCid, ChlorCid V, and ChlorCid Surf are effective for their intended use when applied as directed in the instruction.

Conclusion: These comparisons and tests demonstrate that the ChlorCid family of irrigants are substantially equivalent to the identified predicate in both technology and intended use, and any small differences in technological characteristics do not raise any new questions of safety or efficacy. The comparisons and tests outlined above demonstrate that the ChlorCid family of irrigants are as safe, as effective, and perform as well as the predicate device.