K082470

Inter-Med, Inc. / Vista-Dental, Inc. 2200 Northwestern Ave., Racine, WI 53404

APR - 3 2009

Section G

510(k) Summary

510(k) Summary	This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFRF 807.92
Applicant	Inter-Med, Inc. / Vista-Dental, Inc. 2200 Northwestern Ave, Racine, WI 53404
Contact Person	Name and Title: George Horvat-QA/RA Manager Ph: 262-636-9755 Fax: 262-636-9760
Trade Name	• Sodium Hypochlorite-3% & 6% • 6% Sodium Hypochlorite with wetting agents marketed as Chlor-XTRA™
Classification Name	Cleanser, Root Canal
Common Name	Endodontic Cleanser
Predicate Devices	Pulpdent Sodium Hypochlorite Solution, Pulpdent Corporation, K09662743, Aquatine™ EC Endodontic Cleanser; PuriCore, Inc., K061689; ChlorCid Sodium Hypochlorite Solution, Product Code EKS, Class 1 Exempt from Premarket Notification, manufactured by Ultradent Products, Inc., Registered Establishment # 1718912
Description	Sodium Hypochlorite 3% & 6%: Solutions are 3% & 6% Sodium Hypochlorite in water. Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-XTRA™ is a Sodium Hypochlorite solution in water with alkalizing salt agents to increase the electrical capacity of the solution.
Indications for Use	Sodium Hypochlorite 3% & 6% Solution and Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-XTRA™ are solutions used for debridement and the instrumentation of root canal. Sodium Hypochlorite-3% & 6% and Chlor-XTRA™ 6% are Sodium Hypochlorite in water.
Substantial Equivalence	The product is similar in function and intended use to: • Pulpdent Sodium Hypochlorite Solution, manufactured by Pulpdent Corporation, K962743 • Aquatine™ EC Endodontic Cleanser; manufactured by PuriCore, Inc., K061689 • ChlorCid Sodium Hypochlorite Solution, manufactured by Ultradent Products, Inc. under Registered Establishment # 1718912, Product Code EKS, Class 1 Exempt from Premarket Notification.
Performance	Laboratory analyses are provided in this premarket notification. Sodium Hypochlorite is the standard of care for root canal irrigation. Several published articles supporting this statement have been included in this premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. George Horvat
Quality Manager
Inter-Med, Incorporated
2200 Northwestern Avenue
Racine, Wisconsin 53404

APR - 3 2009

Re: K082470
Trade/Device Name: Sodium Hypochlorite 3% & 6% Solution Sodium Hypochlorite 6% with Wetting Agents to lower Surface Tension Marketed as Chlor-Xtra
Regulation Number: 21 CFR Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: KJJ
Dated: March 30, 2009
Received: March 30, 2009

Dear Mr. Horvat:

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.

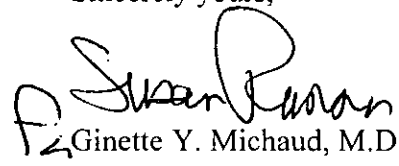
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,



Ginette Y. Michaud, M.D.
Acting 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): K082470

Device Names:

1. Sodium Hypochlorite 3% & 6% Solution
2. Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-Xtra

Indications for Use:

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™ 6 % are Sodium Hypochlorite solutions in water.

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

510(k) Number: K082470