K112250

OCT 2 8 2011

Inter-Med, Inc.
2200 Northwestern Avenue
Racine, WI 53404
(262) 636-9755 (voice)
(262) 636-9760 (fax)

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: John Baeten, Engineering Manager Ph: 262-636-9755 Fax: 262-636-9760
Date Prepared	July 27, 2011
Proprietary Name	• CHX • CHX-Plus™
Classification Name	Cleanser, Root Canal
Common Name	Endodontic Cleanser
CFR Number	N/A
Device Class	Unclassified
Product Code	KJJ
Predicate Device(s)	K070401, Endo-CHX™ Root Canal Cleanser, Essential Dental Systems, Inc. K103244, QMix™ 2inl Endodontic Irrigating Solution,. DENTSPLY International K924982, Consepsis™, Ultradent Products, Inc. K053167, Bioure™ MTADTM Root Canal Cleanser, DENTSPLY International K061689, Aquatine™ EC Endodontic Cleanser, PuriCore, Inc.
Description	CHX and CHX-Plus™ are 2% Chlorhexidine Gluconate Solutions in water. CHX – Plus™ also contains wetting agents to lower surface tension. CHX and CHX-Plus™ are root canal cleansers for use in endodontic procedures. After endodontic instrumentation, these products should be used to cleanse the canal space before placement of the endodontic filling. The material should be delivered into the canal using an irrigating needle.

Indications for Use	CHX and CHX-Plus™ are used as a final endodontic rinse after instrumentation to irrigate and cleanse the root canal system for long lasting cleansing
Substantial Equivalence	CHX and CHX-Plus™ are identical to the predicates since they irrigate and cleanse via the mechanical action of the solution moving through the root canal system. Both CHX-Plus™ and Endo-CHX™ are combination products containing 2% chlorhexidine digluconate with surfactant(s). These items are identical in active ingredient (i.e. 2% chlorhexidine digluconate) and indications for use. Both CHX-Plus™ and Consepsis™ are combination products containing 2% chlorhexidine digluconate and surface active agents to lower surface tension. CHX-Plus™ contains surfactants and Consepsis™ contains ethyl alcohol. CHX / CHX-Plus™, Endo-CHX™, Consepsis™, and QMix™ 2inl Endodontic Irrigating Solution are all root canal cleansers containing chlorhexidine digluconate. CHX-Plus™, Endo-CHX™, QMix™ 2inl Endodontic Irrigating Solution, and BioPure™MTAD™ are all root canal cleansers containing a surfactant to lower surface tension.
Non-clinical Performance	The performance and biocompatibility data provided support the safety and effectiveness of CHX and CHX-Plus™ for the indicated uses. All components found in CHX and CHX-Plus™ have been used in legally marketed devices. The efficacy and biocompatibility was demonstrated via non-clinical studies.
Conclusion	CHX and CHX-Plus™, to be manufactured by Inter-Med Inc., are substantially equivalent to the currently cleared and marketed predicates and raise no issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 28 2011

Mr. John Baeten
Engineering Manager
Inter-Med, Inc.
2200 Northwestern Avenue
Racine, WI 53404

Re: K112250
Trade/Device Name: CHX and CHX-Plus™
Regulation Number: None
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Codes: KJJ
Dated: July 27, 2011
Received: August 4, 2011

Dear Mr. Baeten:

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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): K112250

Device Names:

1. CHX
2. CHX-Plus™

Indications for Use:

CHX and CHX-Plus™ are used as a final endodontic rinse after instrumentation to irrigate and cleanse the root canal system for long lasting cleansing

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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