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K130180

SUMMARY 510 (k)

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	CERKAMED Wojciech Pawlowski Kwiatkowskiego 1 Str. 37-450 Stalowa Wola, POLAND
Contact person	Kinga Wierucka Kwiatkowskiego 1 Str.; 37-450 Stalowa Wola, POLAND Phone: +48 15 842 35 85 Fax: +48 15 842 35 85 e-mail : kinga.wierucka@cerkamed.pl OCT 0 3 2013
Date prepared	05.07.2013
Trade name	CHLORAXID 3% CHLORAXID 5,25%
Common name	Liquid used for root canal rinsing
Classification name	Cleanser root canal
Risk Classification	Unclassified (pre-amendment)
Classification Product Code	KJJ
Predicate devices	Sodium Hypochlorite 3% & 6%; Inter Med Inc/ Vista Dental, K082470 Pulpdent Sodium Hypochlorite Solution, K962743.
Descritpion	Liquid for root canals rinsing
Active ingredient	Sodium Hypochlorite
Indication for use	Liquid used for root canal rinsing during endodontic treatment.
The mode of action	During mechanical canal widening it removes the non-vital pulp debris. It cleans the canal and removes at the same time smear layer in order to expose dentinal tubuli orifices before canal filling.
Contraindications	Do not use products CHLORAXID 3% and CHLORAXID 5,25% for patients with hypersensitivity to the product's components.
Recipient	This device to be sale by or on the order of a dentists. Device qualifies for exemption per 21 CFR 801 D.
Substantial equivalence	The product is similar in function and intended use as well as in technological characterization to: - Sodium Hypochlorite 3%& 6% ; manufactured by Inter Med Inc/ Vista Dental - Pulpdent Sodium Hypochlorite Solution, manufactured by Pulpdent Corp.
Technological characteristic	The main active substance in this device is Sodium Hypochlorite. Sodium Hypochlorite is the standard of care for root canal irrigation. Both products: CHLORAXID 3% and CHLORAXID 5,25% are composed of the same substances, have the same intended use and are substantially equivalent in safety and effectiveness for the indications described as the predicate devices.
Non-clinical performance	The non-clinical performance and biocompatibility data provided in this submission was based on professional literature by comparison with reference device and its chemical composition. Realistic study of biological effect of device CHLORAXID 3 % and CHLORAXID 5,25% has been abandoned because sufficient literature evidence exists for confirmation biological effect of device contained chemical compounds specified

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	in their composition. These data support determination of substantial equivalence: CHLORAXID 3% and CHLORAXID 5,25% are substantially equivalent in safety and effectiveness to the predicate devices. All components found in CHLORAXID 3% & CHLORAXID 5,25% have been used in legally marketed devices.
Conclusion	CHLORAXID 3% is substantially equivalent in safety and effectiveness to Sodium Hypochlorite 3% produced by Vista Dental. CHLORAXID 5,25% is substantially equivalent in safety and effectiveness to the currently cleared and marketed Pulpdent Sodium Hypochlorite Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 3, 2013

P.P.H. Cerkamed Wojciech Pawlowski
C/O Ms. Kinga Wierucka
Project Manager
Kwiatkowskiego 1 Street
37-450 Stalowa Wola
POLAND

Re: K130180
Trade/Device Name: Chloraxid 3% and Chloraxid 5.25%
Regulation Number: None
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: July 5, 2013
Received: July 17, 2013

Dear Ms. Wierucka:

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 contact 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. 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,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATION FOR USE
CHLORAXID 3% & CHLORAXID 5,25%

510(k) Number (if known): K130180

Device Name: CHLORAXID 3% & CHLORAXID 5,25% - Liquid for root canals rinsing

Intended use:

Liquid used for root canal rinsing during endodontic treatment.

During mechanical canal widening it removes the non-vital pulp debris.

It cleans the canal and removes at the same time smear layer in order to expose dentinal tubuli orifices before canal filling.

Prescription Use: *X* AND/OR Over-The-Counter Use -
(Part 21 CFR 801 Subpart D) (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)

Andrew I. Steen -S
2013.10.03 13:11:03 -04'00'