



Office of Combination Products
15800 Crabbs Branch Way (HFG-3)
Suite 200
Rockville, MD 20855

Food and Drug Administration
Rockville MD 20857

June 20, 2007

██████████
Official Correspondent for Essential Dental Systems
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██████████

Re: Request for Designation
Endo-CHX Root Canal Cleanser
Our file: RFD070025
Dated: May 16, 2007
Received and Filed: May 16, 2007
Amended: June 7, 2007¹

Dear ██████████:

The Food and Drug Administration (FDA) has completed its review of the request for designation (RFD) for the Endo-CHX Root Canal Cleanser (Endo-CHX) that you submitted on behalf of Essential Dental Systems. The Office of Combination Products (OCP) received and filed the RFD on May 16, 2007, and received and filed its amendment on June 7, 2007. As explained below, we conclude that Endo-CHX is a combination product, and we have assigned it to the Center for Devices and Radiological Health (CDRH) as the lead agency center for premarket review and regulation based on our determination of the product's primary mode of action (PMOA).

Description of the Product

According to the amended RFD, the product is intended to irrigate and cleanse the root canal systems during the endodontic procedure. The product is an aqueous solution comprised of 2% chlorhexidine digluconate, ██████████. The RFD explains that after the practitioner first removes the smear layer of the canal and then rinses the canal, s/he places the Endo-CHX into an irrigating syringe and uses it to continuously irrigate the canal for a minimum of two minutes. Afterwards, the RFD explains, the practitioner must not rinse, but instead should dry and obdurate the canal.

¹ After the Office of Combination Products received and filed the initial RFD on May 16, 2007, Ms. Goldstein-Falk stated in an email sent to Leigh Hayes on June 7, 2007 that the company wished to amend the RFD to clarify Endo-CHX's mode of action and change its intended use. Consequently, the jurisdictional determination in this letter is based on the product's modes of action and intended use as set forth in the amended RFD.

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You recommend that Endo-CHX be assigned to CDRH because you believe its PMOA is attributable to the device component's action to mechanically flush the canal, which removes the majority of the bacteria from the root canal.

Product Classification: Combination Product

We have determined that, because the product is comprised of device (syringe and various components comprising the aqueous solution) and drug (chlorhexidine digluconate) components, it is a combination product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1) and (2). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, assignment of a lead Center to conduct the review of a combination product is based on the Agency's determination of the product's PMOA.

Assignment of Lead Center: CDRH

We have considered the information in the RFD, and discussed the issues with staff in the Center for Drug Evaluation and Research and CDRH.

This product has two modes of action. One action of the product is the device component's action to mechanically flush the canal, which removes the majority of the bacteria from the canal. Another action of the product is the drug component's action to kill the bacteria remaining in the canal after it has been flushed. As set forth in the amended RFD, your product's modes of action and intended use are similar to other device/drug combination products intended to mechanically cleanse canals and cavities, which have a PMOA attributable to the device component's mechanical cleansing action. Therefore, we have determined that the PMOA of your product is the action of the device component to mechanically flush the canal, which removes the majority of the bacteria from the canal.

Accordingly, we are assigning the product to CDRH for premarket review and regulation under the medical device provisions of the Act. Any clinical investigations of the combination product are subject to the investigational device exemption (IDE) requirements found at 21 CFR 812 and should be conducted in conformity with those regulations. For your information, FDA published a draft guidance document "Current Good Manufacturing Practice for Combination Products," available at <http://www.fda.gov/oc/combination/default.htm>, which provides information about the applicability of current good manufacturing practice regulations for combination products. We encourage you to discuss with CDRH these and other regulatory requirements applicable to your combination product.

CDRH's Division of Anesthesia, General Hospital, Infection Control, and Dental Devices (DAGID), Dental Devices Branch, will be responsible for the combination product's premarket review and regulation. For further information about review requirements and how to proceed with submitting an application to CDRH, please contact Dr. Susan Runner, Chief, Dental Devices Branch, at 240-276-3776. Please include a copy of this letter with your initial submission to CDRH.

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If you have any questions about this letter, please contact me at (301) 427-1934. Finally, the Office of Combination Products is available to you as a resource for questions or issues that may arise throughout the development of your product. You may reach us at the above address or by email at combination@fda.gov.

Sincerely,

A handwritten signature in black ink that reads "Leigh Hayes". The signature is written in a cursive, flowing style.

Leigh Hayes
Product Assignment Officer
Office of Combination Products

cc: Dr. Susan Runner