4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2017-P-5124]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Over-the-Counter Denture Repair Kit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order granting a petition requesting exemption from premarket notification requirements for over-the-counter (OTC) denture repair kits (Product Code EBO). These devices consist of material, such as a resin monomer system of powder and liquid glues, which is intended to be applied permanently to a denture to mend cracks or breaks. This order exempts OTC denture repair kits, class II devices, from premarket notification (510(k)). This exemption from 510(k) is immediately in effect for OTC denture repair kits. FDA is publishing this order in accordance with the section of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The exemption was applicable on January 31, 2018.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993-0002, 301-796-6527.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and its implementing regulations in part 807 (21 CFR part 807) require persons who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k) to FDA. The device may not be marketed until FDA finds it "substantially equivalent" within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115), section 206 of which added section 510(m) to the FD&C Act, as amended on December 13, 2016, by the 21st Century Cures Act (Pub. L. 114-255). Section 510(m)(1) of the FD&C Act, requires FDA to publish in the *Federal Register* a list of each type of class II device that does not require a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the FD&C Act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the *Federal Register*.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a device from premarket notification requirements on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide assurance of the safety and effectiveness of the device. This section requires FDA to publish in the *Federal Register* a notice of intent to exempt a device, or of the petition, and to provide a 60-day comment period. Within 120 days after the issuance of the notice, FDA shall publish an order in the *Federal Register* setting forth the final determination regarding the exemption of the device that was the

subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the Agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff" (Class II 510(k) Exemption Guidance). That guidance can be obtained through the internet at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf or by sending an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the document. Please use the document number 159 to identify the guidance you are requesting.

III. Petition

On August 22, 2017, FDA received a petition requesting an exemption from premarket notification for OTC denture repair kits. (See Docket No. FDA-2017-P-5124.) These devices are currently classified under 21 CFR 872.3570, OTC denture repair kits.

In the *Federal Register* of November 20, 2017 (82 FR 55105), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by January 19, 2018. FDA received no comments.

FDA has assessed the need for 510(k) clearance for this type of device against the criteria laid out in the Class II 510(k) Exemption Guidance. Based on this review, FDA believes that premarket notification is not necessary to provide a reasonable assurance of the safety and

effectiveness of the device, as long as the device complies with existing special controls. FDA agrees that the risks posed by the device and the characteristics of the device necessary for its safe and effective performance are well established. FDA believes that changes in the device that could affect safety and effectiveness will be readily detectable by certain types of routine analysis and nonclinical testing, such as those detailed in the existing special controls. Therefore, after reviewing the petition, FDA has determined that premarket notification is not necessary to provide a reasonable assurance of safety and effectiveness of OTC denture repair kits. FDA responded to the petition by letter dated January 31, 2018, to inform the petitioner of this decision within the 180-day timeframe under section 510(m)(2) of the FD&C Act.

IV. Limitations of Exemption

This final order exempts from premarket notification an OTC denture repair kit. This device will remain subject to the class II special controls under 21 CFR 872.3570 and will be subject to the limitations of exemption found in 21 CFR 872.9.

V. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order refers to previously approved collections of information found in other FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910-0120.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872--DENTAL DEVICES

1. The authority citation for part 872 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

2. In § 872.3570, revise paragraph (b) introductory text to read as follows:

§ 872.3570 OTC denture repair kit.

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(b) *Classification*. Class II. The OTC denture repair kit is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 872.9. The special controls for this device are FDA's:

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Dated: March 8, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-05116 Filed: 3/13/2018 8:45 am; Publication Date: 3/14/2018]