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Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements

Guidance for Industry and Food and Drug Administration Staff

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This document updates and supersedes “Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements,” issued August 14, 2015.

For questions about this document, contact Regulations, Policy, and Guidance Staff by email at RPG@fda.hhs.gov.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to <https://www.regulations.gov>. Submit written comments the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Identify all comments with the docket number FDA-2014-D-0967. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1300046 to identify the guidance you are requesting.

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This guidance represents the current thinking of Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance listed on the title page.

I. Introduction

This guidance describes the Food and Drug Administration's (FDA's) intent to exempt certain unclassified medical devices from premarket notification requirements. FDA believes devices identified in **Section IV** of this guidance document are sufficiently well understood and do not require premarket notification (510(k)) to assure their safety and effectiveness. Until the publication of a final rule exempting these devices from 510(k), FDA does not intend to enforce compliance with 510(k) requirements for these devices. FDA does not expect manufacturers to submit 510(k)s for these devices during this time period.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) (<http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf>) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, FDA committed to identifying low-risk medical devices to exempt from premarket notification requirements. Under the 21st Century Cures Act, FDA was given the authority to exempt class II and class I reserved medical devices from premarket notification requirements on a periodic basis. To date, several class I and class II devices have been

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exempted through 510(l)¹ and 510(m)², respectively, of the Federal Food, Drug, and Cosmetic Act as amended. Therefore, for the purposes of this guidance, FDA has identified certain unclassified medical devices (that FDA intends to classify into class I or II) for which FDA believes premarket notification is not necessary to assure safety and effectiveness before these devices enter the marketplace.

III. Scope

The goal of this document is to outline FDA's intent to propose exempting the unclassified medical devices listed below in **Section IV** from premarket notification requirements. FDA does not intend to exempt these devices from other statutory and regulatory 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 System regulation (21 CFR part 820); and Medical Device Reporting requirements (21 CFR part 803). It is not FDA's intent to exempt any combination products that may fall within the product codes subject to this guidance. Also, single-entity products containing an antimicrobial agent are not within the scope of this guidance.

IV. Unclassified Devices FDA Intends to Exempt from Premarket Notification Requirements

A. Ear, Nose, and Throat Devices

Preamendment unclassified devices – FDA intends to exempt the following product codes:

EWD – Protector, Hearing (Insert)

EWE – Protector, Hearing (Circumaural)

LEZ – Aids, Speech Training for the Hearing Impaired (AC-Powered and Patient-Contact)

LFA – Aids, Speech Training for the Hearing Impaired (Battery-Operated or Non-Patient)

B. Gastroenterology-Urology Devices

Preamendment unclassified device – FDA intends to exempt the following product code:

LRL – Cushion, Hemorrhoid

C. General and Plastic Surgical Devices

Preamendment unclassified device – FDA intends to exempt the following product code:

LKB – Pad, Alcohol, Device Disinfectant

¹ 82 FR 17841

² 82 FR 31976 and 83 FR 25910

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D. Neurological Devices

Preamendment unclassified devices – FDA intends to exempt the following product codes:

LLN – Device, Vibration Threshold Measurement. This intention does not apply to devices that provide an interpretation or a clinical implication of the measurement.

LQW – Test, Temperature Discrimination. This intention does not apply to devices that provide an interpretation or a clinical implication of the measurement.

E. Obstetrical and Gynecological Devices

Preamendment unclassified devices – FDA intends to exempt the following product code:

LHD – Device, Fertility Diagnostic, Proceptive

F. Physical Medicine Devices

Preamendment unclassified devices – FDA intends to exempt the following product code:

LZW – Monitor, Spine Curvature