Contains Nonbinding Recommendations

Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements

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Guidance for Industry and Food and Drug Administration Staff

Document issued on June 5, 2026.

Document originally issued on July 1, 2015.

This document updates and supersedes "Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements," issued June 14, 2019.

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

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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 to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. 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 GUI1300046 and complete title of the guidance in the request.

Table of Contents

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This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) 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 or Office responsible for this guidance as 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. At this time, and based on the information currently available to the Agency, FDA believes the devices identified in **Section IV** of this guidance document meet the standards for exemption from premarket notification (510(k)) requirements. Until such exemption occurs, or until FDA becomes aware of new information affecting its current understanding, FDA does not intend to enforce compliance with 510(k) requirements for these devices. Due to this enforcement policy, FDA does not expect manufacturers to submit 510(k)s for these devices during this time period.

This guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

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 I.G of the Performance Goals and Procedures) (https://www.fda.gov/media/83244/download) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), FDA committed to proposing low-risk medical devices to exempt from premarket notification requirements. The first iteration of this guidance noted that FDA intended to exempt from premarket notification certain unclassified medical devices (that FDA intended to classify into class I or II), certain class II medical devices, and certain class I "reserved" medical devices (that FDA believed no longer met the "reserved" criteria at section 510(l) of the FD&C Act[1]). Subsequently, section 3054 of the 21st Century Cures Act amended sections 510(l) and 510(m) of the FD&C Act to require FDA to exempt eligible class I "reserved" and class II medical devices, respectively, from premarket notification requirements on a periodic basis. Classified device types previously included in this guidance have since been exempted and removed. Therefore, the present guidance identifies only certain unclassified medical devices that FDA currently believes meet the standards for exemption from premarket notification.

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 propose exempting 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 Management System Regulation (21 CFR part 820); and Medical Device Reporting (21 CFR part 803). It is not FDA's intent to propose exempting from premarket notification requirements any combination products, including single-entity products containing an antimicrobial agent, that may fall within the product codes listed in 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:

[1] Section 510(l)(1) provides that the statutory 510(k) exemption for class I devices "does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury." FDA refers to these two criteria as the "reserved" criteria.

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 devices – FDA intends to exempt the following product codes:

LKB – Pad, Alcohol, Device Disinfectant
MQZ – Prosthesis, Nail

D. Obstetrical and Gynecological Devices

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

LHD – Device, Fertility Diagnostic, Proceptive

E. Physical Medicine Devices

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

LDK – Device, Sensing, Optical Contour
LZW – Monitor, Spine Curvature

F. Neurological Devices

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

MVV – Device, Acupressure

G. Toxicology Devices

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

MIG – Strip, Test Isoniazid

H. Ophthalmic Devices

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

LXQ – Cup, Eye

Guidance History[*]	**Date**	**Description**
Level 1 IIE	June 2026	Five additional preamendment unclassified devices were added to this guidance.
Level 2 Guidance	June 2019	Consistent with Level 2 guidance procedures (21 CFR 10.115(g)(4)), a NOA was not issued for this guidance.

*This table was implemented, beginning June 2025, and previous guidance history may not be captured in totality.

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