# Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements

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# Draft Guidance for Industry and Food and Drug Administration Staff

***DRAFT GUIDANCE***

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

# Preface

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# Draft Guidance for Industry and Food and Drug Administration Staff

***This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.***

## 1. Introduction

This draft guidance describes the FDA's intent to exempt certain Class II medical devices and certain Class I medical devices that are subject to the reserved criteria of section 510(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 360(l), from premarket submission requirements. The FDA believes devices identified in section 4 of this guidance document are sufficiently well understood and do not present risks that require premarket notification (510(k)) review to assure their safety and effectiveness. FDA intends to propose exempting these devices from premarket notification pursuant to the criteria at sections 510(l) and 510(m) of the FD&C Act, subject to limitations on exemption criteria found in 21 CFR 868.9, 21 CFR 870.9, 21 CFR 872.9, 21 CFR 874.9, 21 CFR 876.9, 21 CFR 878.9, CFR 880.9, 21 CFR 882.9, 21 CFR 884.9, 21 CFR 886.9, and 21 CFR 890.9. Notice of such a proposal would be provided in the Federal Register. Until the publication of a final rule or order 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.

# 2. 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 re-authorization process for the Medical Device User Fee Amendments of 2012, FDA committed to identifying low risk medical devices to exempt from premarket notification. FDA has identified certain Class II medical devices for which FDA believes a 510(k) review is not necessary to assure safety and effectiveness before these devices enter the market place, and certain Class I medical devices which FDA believes no longer meet the "reserved" criteria at section 510(l) of the FD&C Act.

# 3. Scope

The goal of this document is to outline FDA's intent to propose exempting the Class II and Class I reserved medical devices listed below in section 4 from premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 868.9, 21 CFR 870.9, 21 CFR 872.9, 21 CFR 874.9, 21 CFR 876.9, 21 CFR 878.9, CFR 880.9, 21 CFR 882.9, 21 CFR 884.9, 21 CFR 886.9, and 21 CFR 890.9. 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 and 21 CFR 809.10); 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).

# 4. Class II and Class I Devices for Which FDA Intends to Exempt from Premarket Notification Requirements

**Anesthesiology Devices**

Devices classified under 21 CFR 868.1040 Powered algesimeter, which includes the following product code:

BSI - Powered Algesimeter

Devices classified under 21 CFR 868.2385 Nitrogen dioxide analyzer, which includes the following product code:

MRQ - Analyzer, Nitrogen Dioxide

Devices classified under 21 CFR 868.2500 Cutaneous oxygen (PcO2) monitor, which includes the following product codes:

KLK - Monitor, Oxygen, Cutaneous, For Infant Not Under Gas Anesthesia

LPP - Monitor, Oxygen, Cutaneous, For Uses Other Than For Infant Not Under Gas Anesthesia

Devices classified under 21 CFR 868.2550 Pneumotachometer, which includes the following product code:

JAX - Pneumotachometer

Devices classified under 21 CFR 868.5180 Rocking bed, which includes the following product code:

CCO - Bed, Rocking, Breathing Assist

Devices classified under 21 CFR 868.6250 Portable air compressor, which includes the following product code:

BTI – Compressor, Air, Portable

## Cardiovascular Devices

Devices classified under 21 CFR 870.1390 Trocar, which includes the following product code:

DRC - Trocar

Devices classified under 21 CFR 870.1875 Stethoscope, which includes the following product code:

OCR - Lung Sound Monitor

Devices classified under 21 CFR 870.2675 Oscillometer, which includes the following product code:

DRZ - Oscillometer

Devices classified under 21 CFR 870.2770 Impedance plethysmograph, which includes the following product code:

MNW - Analyzer, Body Composition with the following labeling: *Not to diagnose or treat any medical condition*. If the labeling or intended use suggests use with a specific medical condition, then a 510(k) submission would still be required.

## Dental Devices

Devices classified under 21 CFR 872.1720 Pulp tester, which includes the following product code:

EAT - Tester, Pulp

Devices classified under 21 CFR 872.3540 OTC denture cushion or pad, which includes the following product codes:

EHR - Pad, Denture, Over The Counter
EHS - Cushion, Denture, Over The Counter

Devices classified under 21 CFR 872.3560 OTC denture reliner, which includes the following product code:

EBP - Reliner, Denture, Over The Counter

Devices classified under 21 CFR 872.3590 Preformed plastic denture tooth, which includes the following product code:

ELM - Denture, Plastic, Teeth

Devices classified under 21 CFR 872.3600 Partially fabricated denture kit, which includes the following product code:

EKO – Denture Preformed (Partially Prefabricated Denture)

Devices classified under 21 CFR 872.3890 Endodontic stabilizing splint, which includes the following product code:

ELS - Splint, Endodontic, Stabilizing

Devices classified under 21 CFR 872.4565 Dental hand instrument, which includes the following product code:

EGI - Parallelometer

Devices classified under 21 CFR 872.5550 Teething ring, which includes the following product code:

KKO - Ring, Teething, Fluid-Filled

**Ear, Nose & Throat Devices**

Devices classified under 21 CFR 874.3310 Hearing aid calibrator and analysis system, which includes the following product code:

ETW - Calibrator, Hearing Aid / Earphone And Analysis System

Devices classified under 21 CFR 874.3320 Group hearing aid or group auditory trainer, which includes the following product code:

EPF - Hearing Aid, Group And Auditory Trainer

Devices classified under 21 CFR 874.3330 Master hearing aid, which includes the following product code:

KHL - Hearing Aid, Master

Devices classified under 21 CFR 874.3430 Middle ear mold, which includes the following product code:

ETC - Mold, Middle-ear

**Gastroenterology - Urology Devices**

Devices classified under 21 CFR 876.1500 Endoscope and accessories, which includes the following product codes:

FCW - Light Source, Fiberoptic, Routine
GCT - Light Source, Endoscope, Xenon Arc
NTN - Led Light Source

Devices classified under 21 CFR 876.4020 Fiberoptic light ureteral catheter, which includes the following product code:

FCS - Light, Catheter, Fiberoptic, Glass, Ureteral

Devices classified under 21 CFR 876.4270 Colostomy rod, which includes the following product code:

EZP - Rod, Colostomy

Devices classified under 21 CFR 876.4400 Hemorrhoidal ligator, which includes the following product codes:

FHN - Ligator, Hemorrhoidal
MND - Ligator, Esophegeal

Devices classified under 21 CFR 876.4500 Mechanical lithotriptor, which includes the following product code:

LQC - Lithotriptor, Biliary Mechanical

Devices classified under 21 CFR 876.4770 Urethrotome, which includes the following product code:

EZO - Urethrotome

Devices classified under 21 CFR 876.5160 Urological clamp for males, which includes the following product code:

MNG - External Urethral Occluder, Urinary Incontinence-Control, Female

Devices classified under 21 CFR 876.5365 Esophageal dilator, which includes the following product codes:

EZM - Dilator, Esophageal (Metal Olive) Gastro-urology
FAT - Bougie, Esophageal, And Gastrointestinal, Gastro-urology
KNQ - Dilator, Esophageal

Devices classified under 21 CFR 876.5665 Water purification system for hemodialysis, which includes the following product code:

NIH - Disinfectant, Subsystem, Water Purification

Devices classified under 21 CFR 876.5895 Ostomy irrigator, which includes the following product code:

EXD - Irrigator, Ostomy

## General and Plastic Surgical Devices

Pre-Amendment unclassified device with the following product code:

LKB - Pad, Alcohol, Device Disinfectant

Devices classified under 21 CFR 878.4014 Nonresorbable gauze/sponge for external use, which includes the following product code:

OVR- Kit, First Aid, Talking

Devices classified under 21 CFR 878.4370 Surgical drape and drape accessories, which includes the following product codes:

ERY - Drape, Surgical, Ent
EYX - Drape, Pure Latex Sheet, With Self-retaining Finger Cot
EYY - Drape, Urological, Disposable
FNW - Pad, Kelly
HMT - Drape, Patient, Ophthalmic
HMW - Drape, Microscope, Ophthalmic
KGW - Ring (Wound Protector), Drape Retention, Internal
KKX - Drape, Surgical

Devices classified under 21 CFR 878.4580 Surgical lamp, which includes the following product codes:

FSQ - Light, Surgical, Instrument
FSS - Light, Surgical, Floor Standing
FSW - Light, Surgical, Endoscopic
FSX - Light, Surgical, Connector
FSY - Light Surgical, Celling mounted
FSZ - Light, Surgical, Carrier
FTD - Lamp, Surgical
FTG - Illuminator, Remote
FQP - Lamp, Operating-room
GBC - lamp, Surgical, Incandescent

Devices classified under 21 CFR 878.5070 Air-handling apparatus for a surgical operating room, which includes the following product codes:

FZG - Apparatus, Air Handling, Bench
FZH - Apparatus, Air Handling, Room
FZI - Apparatus, Air Handling, Enclosure

**General Hospital and Personal Use Devices**

Devices classified under 21 CFR 880.2910 Clinical electronic thermometer, which includes the following product code:

FLL - Thermometer, Electrical, Clinical

Devices classified under 21 CFR 880.5780 Medical support stocking, which includes the following product code:

DWL - Stocking, Medical Support (To Prevent Pooling Of Blood in Legs)

Devices classified under 21 CFR 880.6250 Patient examination glove, which includes the following product code:

LZB - Finger Cot

Devices classified under 21 CFR 880.6710 Medical ultraviolet water purifier, which includes the following product code:

KMG – Purifier, Water, Ultraviolet, Medical

Devices classified under 21 CFR 880.6760 Protective restraint, which includes the following product codes:

BRT - Restraint, Patient, Conductive

FMQ - Restraint, Protective

## Neurological Devices

Pre-Amendment unclassified devices with the following product codes:

LLN - Device, Vibration Threshold Measurement. If device contains software to analyze clinical implication of the measurement, a 510(k) will be required.

LQW - Test, Temperature Discrimination. If device contains software to analyze clinical implication of the measurement, a 510(k) will be required.

Devices classified under 21 CFR 882.1030 Ataxiagraph, which includes the following product code:

GWW – Ataxiagraph. If device contains software to analyze clinical implication of the measurement a 510(k) will be required.

Devices classified under 21 CFR 882.5320 Preformed alterable cranioplasty plate, which includes the following product code:

GWO - Plate, Cranioplasty, Preformed, Alterable

## Obstetrical and Gynecological Devices

Pre-Amendment unclassified devices with the following product code:

LHD - Device, Fertility Diagnostic, Proceptive

Devices classified under 21 CFR 884.3200 Cervical drain, which includes the following product code:

HFL - Drain, Cervical

Devices classified under 21 CFR 884.4400 Obstetric forceps, which includes the following product code:

HDA - Forceps, Obstetrical

Devices classified under 21 CFR 884.4530 Obstetric-gynecologic specialized manual instrument, which includes the following product codes:

HIB - Speculum, Vaginal, Nonmetal

HFW - Clamp, Umbilical

Devices classified under 21 CFR 884.5200 Hemorrhoid prevention pressure wedge, which includes the following product code:

OOA – Hemorrhoid, Prevention, Pressure, Wedge

Devices classified under 21 CFR 884.5390 Perineal heater, which includes the following product codes:

HGZ - Heater, Perineal, Direct Contact
HHA - Heater, Perineal, Radiant, Non-contact
KND - Heater, Perineal

Devices classified under 21 CFR 884.5400 Menstrual cup, which includes the following product code:

HHE - Cup, Menstrual

Devices classified under 21 CFR 884.5435 Unscented menstrual pad, which includes the following product code:

NUQ - Pad, Menstrual, Reusable

Devices classified under 21 CFR 884.5960 Genital vibrator for therapeutic use, which includes the following product code:

KXQ – Vibrator For Therapeutic Use, Genital

**Ophthalmic Devices**

Devices classified under 21 CFR 886.1120 Ophthalmic camera, which includes the following product codes:

HKI - Camera, Ophthalmic, AC-powered
MMF - Photorefractor

Devices classified under 21 CFR 886.1250 Euthyscope, which includes the following product code:

HMK - Euthyscope, AC-powered

Devices classified under 21 CFR 886.1945 Transilluminator, which includes the following product code:

HJM - Transilluminator, AC-powered

Devices classified under 21 CFR 886.4070 Powered corneal burr, which includes the following product codes:

HLD - Engine, Trephine, Accessories, Gas-powered
HOG - Burr, Corneal, Battery-powered
HRF - Engine, Trephine, Accessories, Battery-powered
HRG - Engine, Trephine, Accessories, AC-powered
HQS - Burr, Corneal, AC-powered

Devices classified under 21 CFR 886.4250 Ophthalmic electrolysis unit, which includes the following product code:

HRO - Unit, Electrolysis, AC-powered, Ophthalmic

Devices classified under 21 CFR 886.4335 Operating headlamp, which includes the following product codes:

FCT - Headlight, Fiberoptic Focusing
FSR - Light, Headband, Surgical
HPQ - Headlamp, Operating, AC-powered

Devices classified under 21 CFR 886.4400 Electronic metal locator, which includes the following product code:

HPM - Locator, Metal, Electronic

Devices classified under 21 CFR 886.4440 AC-powered magnet, which includes the following product code:

HPO - Magnet, AC-Powered

Devices classified under 21 CFR 886.4790 Ophthalmic sponge, which includes the following product code:

HOZ - Sponge, Ophthalmic

**Physical Medicine Devices**

Devices classified under 21 CFR 890.1450 Powered reflex hammer, which includes the following product code:

IKO - Hammer, Reflex, Powered

Devices classified under 21 CFR 890.3475 Limb orthosis, which includes the following product code:

LQX - Device, Finger-sucking

Devices classified under 21 CFR 890.5100 Immersion hydrobath, which includes the following product codes:

ILJ -Bath, Hydro-massage
ILM - Bath, Sitz, Powered

Devices classified under 21 CFR 890.5110 Paraffin bath, which includes the following product code:

IMC - Bath, Paraffin

Devices classified under 21 CFR 890.5360 Measuring exercise equipment, which includes the following product code:

ISD - Exerciser, Measuring

Devices classified under 21 CFR 890.5575 Powered external limb overload warning device, which includes the following product code:

IRN – Device, Warning, Overload, External Limb, Powered