

The 21st Century Cures Act (Cures), signed into law on December 13, 2016, amended several sections of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of Cures, and certain sections of this guidance may no longer be current as a result. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information please contact DICE@fda.hhs.gov.

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

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 14, 2015.

**This document updates and supersedes “Intent to Exempt Certain
Unclassified, Class II, and Class I Reserved Medical Devices from
Premarket Notification Requirements,” issued July 1, 2015.**

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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

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, 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.

Table of Contents

I.	Introduction	4
II.	Background	5
III.	Scope	5
IV.	Unclassified, Class II, and Class I Devices FDA Intends to Exempt from Premarket Notification	
	Requirements	5
	Anesthesiology Devices	5
	Cardiovascular Devices	6
	Dental Devices	7
	Ear, Nose & Throat Devices	8
	Gastroenterology - Urology Devices	8
	General and Plastic Surgical Devices	10
	General Hospital and Personal Use Devices	10
	Neurological Devices	11
	Obstetrical and Gynecological Devices	12
	Ophthalmic Devices	13
	Physical Medicine Devices	14

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Guidance for Industry and Food and Drug Administration Staff

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) intent to exempt certain unclassified medical devices, 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 notification requirements. The 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. FDA intends to propose exempting these devices from premarket notification requirements 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, 21 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.

Contains Nonbinding Recommendations

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 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 requirements. FDA has identified certain unclassified medical devices (that FDA intends to classify into Class I or II), certain Class II medical devices, and certain Class I reserved medical devices (that no longer meet the “reserved” criteria at section 510(l) of the FD&C Act) 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, Class II, and Class I reserved medical devices listed below in section IV 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, 21 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); 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, Class II, and Class I Devices FDA Intends to Exempt from Premarket Notification Requirements

Anesthesiology Devices

Devices classified under 21 CFR 868.1040 Powered algometer – FDA intends to exempt the following product code:

BSI - Powered Algometer

Contains Nonbinding Recommendations

Devices classified under 21 CFR 868.2385 Nitrogen dioxide analyzer – FDA intends to exempt the following product code:

MRQ - Analyzer, Nitrogen Dioxide. This intention only applies to stand-alone devices and not those that are components of nitric oxide delivery systems used to monitor nitrogen dioxide levels during inhaled nitric oxide therapy.

Devices classified under 21 CFR 868.2500 Cutaneous oxygen (PcO₂) monitor – FDA intends to exempt 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 – FDA intends to exempt the following product code:

JAX - Pneumotachometer

Devices classified under 21 CFR 868.5180 Rocking bed – FDA intends to exempt the following product code:

CCO - Bed, Rocking, Breathing Assist

Devices classified under 21 CFR 868.6250 Portable air compressor – FDA intends to exempt the following product code:

BTI - Compressor, Air, Portable

Cardiovascular Devices

Devices classified under 21 CFR 870.1390 Trocar – FDA intends to exempt the following product code:

DRC - Trocar

Devices classified under 21 CFR 870.1875 Stethoscope – FDA intends to exempt the following product code:

OCR - Lung Sound Monitor

Devices classified under 21 CFR 870.2675 Oscillometer – FDA intends to exempt the following product code:

DRZ - Oscillometer

Devices classified under 21 CFR 870.2770 Impedance plethysmograph – FDA intends to exempt the following product code:

MNW - Analyzer, Body Composition with the following labeling: *Not to diagnose or treat any medical condition*. This intention does not apply to devices where the labeling or intended use suggests use with a specific medical condition.

Contains Nonbinding Recommendations

Devices classified under 21 CFR 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting – FDA intends to exempt the following product code:

DTL – Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass

Dental Devices

Devices classified under 21 CFR 872.1720 Pulp tester – FDA intends to exempt the following product code:

EAT - Tester, Pulp

Devices classified under 21 CFR 872.3540 OTC denture cushion or pad – FDA intends to exempt 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 – FDA intends to exempt the following product code:

EBP - Reliner, Denture, Over The Counter

Devices classified under 21 CFR 872.3590 Preformed plastic denture tooth – FDA intends to exempt the following product code:

ELM - Denture, Plastic, Teeth

Devices classified under 21 CFR 872.3600 Partially fabricated denture kit – FDA intends to exempt the following product code:

EKO - Denture Preformed (Partially Prefabricated Denture)

Devices classified under 21 CFR 872.3890 Endodontic stabilizing splint – FDA intends to exempt the following product code:

ELS - Splint, Endodontic Stabilizing

Devices classified under 21 CFR 872.4565 Dental hand instrument – FDA intends to exempt the following product codes:

EGI - Parallelometer

EIB - Syringe, Irrigating (Dental)

Devices classified under 21 CFR 872.5550 Teething ring – FDA intends to exempt the following product code:

KKO - Ring, Teething, Fluid-Filled

Contains Nonbinding Recommendations

Ear, Nose & Throat Devices

Pre-Amendment 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)

Devices classified under 21 CFR 874.1325 Electroglottograph – FDA intends to exempt the following product code:

KLX – Electroglottograph

Devices classified under 21 CFR 874.3310 Hearing aid calibrator and analysis system – FDA intends to exempt 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 – FDA intends to exempt the following product codes:

EPF - Hearing Aid, Group And Auditory Trainer

LZI – Device, Assistive Listening

Devices classified under 21 CFR 874.3330 Master hearing aid – FDA intends to exempt the following product code:

KHL - Hearing Aid, Master

Devices classified under 21 CFR 874.3430 Middle ear mold – FDA intends to exempt the following product code:

ETC - Mold, Middle-ear

Gastroenterology - Urology Devices

Pre-Amendment unclassified device – FDA intends to exempt the following product code:

LRL – Cushion, Hemorrhoid

Devices classified under 21 CFR 876.1500 Endoscope and accessories – FDA intends to exempt the following product codes:

FCW - Light Source, Fiberoptic, Routine

GCT - Light Source, Endoscope, Xenon Arc

NTN - Led Light Source

OCY - Endoscopic Guidewire, Gastroenterology-urology

Devices classified under 21 CFR 876.4020 Fiberoptic light ureteral catheter – FDA intends to exempt the following product code:

Contains Nonbinding Recommendations

FCS - Light, Catheter, Fiberoptic, Glass, Ureteral

Devices classified under 21 CFR 876.4270 Colostomy rod – FDA intends to exempt the following product code:

EZP - Rod, Colostomy

Devices classified under 21 CFR 876.4400 Hemorrhoidal ligator – FDA intends to exempt the following product codes:

FHN - Ligator, Hemorrhoidal

MND - Ligator, Esophageal

Devices classified under 21 CFR 876.4500 Mechanical lithotripter – FDA intends to exempt the following product code:

LQC - Lithotripter, Biliary Mechanical

Devices classified under 21 CFR 876.4770 Urethrotome – FDA intends to exempt the following product code:

EZO - Urethrotome

Devices classified under 21 CFR 876.5160 Urological clamp for males – FDA intends to exempt the following product code:

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

Devices classified under 21 CFR 876.5365 Esophageal dilator – FDA intends to exempt 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 876.5520 Urethral dilator – FDA intends to exempt the following product codes:

KOE - Dilator, Urethral

Devices classified under 21 CFR 876.5665 Water purification system for hemodialysis – FDA intends to exempt the following product code:

NIH - Disinfectant, Subsystem, Water Purification

Devices classified under 21 CFR 876.5895 Ostomy irrigator – FDA intends to exempt the following product code:

EXD - Irrigator, Ostomy

Contains Nonbinding Recommendations

General and Plastic Surgical Devices

Pre-Amendment unclassified device – FDA intends to exempt the following product code:

LKB - Pad, Alcohol, Device Disinfectant

Devices classified under 21 CFR 878.4014 Nonresorbable gauze/sponge for external use – FDA intends to exempt the following product code:

OVR- Kit, First Aid, Talking

Devices classified under 21 CFR 878.4370 Surgical drape and drape accessories – FDA intends to exempt 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. This intention does not apply to devices including an antimicrobial agent.

Devices classified under 21 CFR 878.4580 Surgical lamp – FDA intends to exempt the following product codes:

FSQ - Light, Surgical, Instrument

FSS - Light, Surgical, Floor Standing

FSW - Light, Surgical, Endoscopic

FSX - Light, Surgical, Connector

FSY - Light Surgical, Ceiling mounted

FSZ - Light, Surgical, Carrier

FTA – Light, Surgical, Accessories

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 – FDA intends to exempt 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 880.5780 Medical support stocking – FDA intends to exempt the following product code:

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

Contains Nonbinding Recommendations

Devices classified under 21 CFR 880.6250 Patient examination glove – FDA intends to exempt the following product code:

LZB - Finger Cot

Devices classified under 21 CFR 880.6375 Patient lubricant – FDA intends to exempt the following product code:

KMJ – Lubricant, Patient

Devices classified under 21 CFR 880.6710 Medical ultraviolet water purifier -- FDA intends to exempt the following product code:

KMG - Purifier, Water, Ultraviolet, Medical

Devices classified under 21 CFR 880.6760 Protective restraint – FDA intends to exempt the following product codes:

BRT - Restraint, Patient, Conductive

FMQ - Restraint, Protective

OYS - Patient Bed With Canopy/Restraints

Neurological Devices

Pre-Amendment 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.

Devices classified under 21 CFR 882.1020 Rigidity analyzer – FDA intends to exempt the following product code:

GZM – Analyzer, Rigidity.

Devices classified under 21 CFR 882.1030 Ataxiagraph¹ – FDA intends to exempt the following product code:

GWW - Ataxiagraph. This intention does not apply to devices that provide an interpretation or a clinical implication of the measurement.

Devices classified under 21 CFR 882.1540 Galvanic skin response measurement device – FDA intends to exempt the following product code:

GZO - Device, Galvanic Skin Response Measurement

¹ Please note that 21 CFR 882.1030 Ataxiagraph is classified as class I (general controls). In 2001, a correction was issued in the FR (see 66 FR 46951-46952) regarding this regulation, which states in part: "As published, an exemption from the premarket notification requirements and a reference to the general limitations language was inadvertently added to 12 device classifications that should not include the reference. These devices are not exempt from the requirements of premarket notification."

Contains Nonbinding Recommendations

Devices classified under 21 CFR 882.1560 Skin potential measurement device – FDA intends to exempt the following product code:

HCJ - Device, Skin Potential Measurement

Devices classified under 21 CFR 882.4060 Ventricular cannula – FDA intends to exempt the following product code:

HCD - Cannula, Ventricular

Devices classified under 21 CFR 882.4545 Shunt system implantation instrument – FDA intends to exempt the following product code:

GYK - Instrument, Shunt System Implantation

Obstetrical and Gynecological Devices

Pre-Amendment unclassified devices – FDA intends to exempt the following product code:

LHD - Device, Fertility Diagnostic, Proceptive

Devices classified under 21 CFR 884.2982 Liquid crystal thermographic system – FDA intends to exempt the following product codes:

LHM – System, Thermographic, Liquid Crystal

KYA – System, Thermographic Liquid Crystal, Nonpowered (Adjunctive Use)

Devices classified under 21 CFR 884.3200 Cervical drain – FDA intends to exempt the following product code:

HFL - Drain, Cervical

Devices classified under 21 CFR 884.4400 Obstetric forceps – FDA intends to exempt the following product code:

HDA - Forceps, Obstetrical

Devices classified under 21 CFR 884.4530 Obstetric-gynecologic specialized manual instrument – FDA intends to exempt the following product codes:

HIB - Speculum, Vaginal, Nonmetal

HFW - Clamp, Umbilical

Devices classified under 21 CFR 884.5200 Hemorrhoid prevention pressure wedge – FDA intends to exempt the following product code:

OOA – Hemorrhoid, Prevention, Pressure, Wedge

Devices classified under 21 CFR 884.5390 Perineal heater – FDA intends to exempt the following product codes:

HGZ - Heater, Perineal, Direct Contact

HHA - Heater, Perineal, Radiant, Non-contact

KND - Heater, Perineal

Contains Nonbinding Recommendations

Devices classified under 21 CFR 884.5400 Menstrual cup – FDA intends to exempt the following product code:

HHE - Cup, Menstrual

Devices classified under 21 CFR 884.5435 Unscented menstrual pad – FDA intends to exempt the following product codes:

NUQ - Pad, Menstrual, Reusable

NUR – Pad, Interlabial

Devices classified under 21 CFR 884.5960 Genital vibrator for therapeutic use – FDA intends to exempt the following product code:

KXQ - Vibrator For Therapeutic Use, Genital

Ophthalmic Devices

Devices classified under 21 CFR 886.1120 Ophthalmic camera – FDA intends to exempt the following product codes:

PJZ - Camera, Ophthalmic, AC-Powered, General-Use

MMF - Photorefractor

Devices classified under 21 CFR 886.1250 Euthyscope – FDA intends to exempt the following product code:

HMK - Euthyscope, AC-powered

Devices classified under 21 CFR 886.1570 Ophthalmoscope – FDA intends to exempt the following product code:

HLJ - Ophthalmoscope, Battery-powered

Devices classified under 21 CFR 886.1945 Transilluminator – FDA intends to exempt the following product code:

HJM - Transilluminator, AC-powered

Devices classified under 21 CFR 886.4070 Powered corneal burr – FDA intends to exempt 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 – FDA intends to exempt the following product code:

HRO - Unit, Electrolysis, AC-powered, Ophthalmic

Contains Nonbinding Recommendations

Devices classified under 21 CFR 886.4335 Operating headlamp – FDA intends to exempt 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 – FDA intends to exempt the following product code:

HPM - Locator, Metal, Electronic

Devices classified under 21 CFR 886.4440 AC-powered magnet – FDA intends to exempt the following product code:

HPO - Magnet, AC-Powered

Devices classified under 21 CFR 886.4790 Ophthalmic sponge – FDA intends to exempt the following product code:

HOZ - Sponge, Ophthalmic

Physical Medicine Devices

Pre-Amendment unclassified devices – FDA intends to exempt the following product code:

LZW – Monitor, Spine Curvature

Devices classified under 21 CFR 890.1450 Powered reflex hammer – FDA intends to exempt the following product code:

IKO - Hammer, Reflex, Powered

Devices classified under 21 CFR 890.5100 Immersion hydrobath – FDA intends to exempt the following product codes:

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

Devices classified under 21 CFR 890.5110 Paraffin bath – FDA intends to exempt the following product code:

IMC - Bath, Paraffin

Devices classified under 21 CFR 890.5360 Measuring exercise equipment – FDA intends to exempt the following product code:

ISD - Exerciser, Measuring

Devices classified under 21 CFR 890.5575 Powered external limb overload warning device – FDA intends to exempt the following product code:

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