

Guidance for Industry and Food and Drug Administration Staff

Enforcement Policy for Premarket Notification Requirements for Certain *In Vitro* Diagnostic and Radiology Devices

Document issued on: December 20, 2011

The draft of this document was issued on July 12, 2011.

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Preface

Public Comment

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Guidance for Industry and Food and Drug Administration Staff

Enforcement Policy for Premarket Notification Requirements for Certain *In Vitro* Diagnostic and Radiology Devices

This guidance represents 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.

A. Introduction

This document is intended to describe FDA's intent with regard to enforcement of premarket notification (510(k)) requirements for certain *in vitro* diagnostic and radiology devices under 21 CFR Part 807, Subpart E. FDA intends to propose the downclassification and exemption from 510(k) requirements of the class II devices that are the subject of this guidance document because it believes the safety and effectiveness of these devices is sufficiently well established and they have sufficiently controlled risks that general controls are sufficient and a 510(k) review is not necessary to assure the safety and effectiveness of such devices, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9. For the Class I devices that are the subject of this guidance document, FDA intends to propose an amendment to the classification regulations to exempt these devices from 510(k) requirements that currently apply under the reserved criteria of section 510(l) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), subject to the limitations on exemption criteria found in 21 CFR 862.9. See 65 FR 2296. In the interim period while FDA proposes and finalizes such downclassification and exemption, FDA intends to

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exercise enforcement discretion with regard to 510(k) submission requirements for the devices listed in this guidance.

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.

B. Background

FDA has identified certain Class I and Class II *in vitro* diagnostic (IVD) and radiology devices that have established safety and effectiveness profiles and for which it believes 510(k) review is not necessary to assure safety and effectiveness. While FDA intends to exempt these devices from the 510(k) requirement through rulemaking that would reclassify the Class II devices and amend the classification regulations of the Class I devices, FDA no longer believes it is necessary to review premarket notification (510(k)) submissions for these devices before they enter the market and intends to exercise enforcement discretion for these devices concerning the 510(k) requirement. The devices identified in this guidance as subject to enforcement discretion with regard to premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9, are listed in section D. FDA intends to continue to enforce all of the FD&C Act's other 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 (QS reg) (21 CFR Part 820); and Medical Device Reporting (MDR) requirements (21 CFR Part 803). This action is being taken as an interim measure in anticipation of a rule reclassifying identified Class II devices as Class I and exempting all of these devices from premarket review.

C. Scope

The goal of this document is to outline FDA's enforcement policy with regard to premarket notification requirements for certain *in vitro* diagnostic and radiology devices listed below in section D, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9.

D. *In Vitro* Diagnostic and Radiology Devices for Which FDA Intends to Exercise Enforcement Discretion With Regard to Premarket Notification Requirements

The devices subject to enforcement discretion:

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Clinical Chemistry Devices

Devices classified under 21 CFR 862.1410 Iron (non-heme) test system, which includes the following product codes:

- CFM - Bathophenanthroline, Colorimetry, Iron (Non-Heme)
- JYI - Photometric Method, Iron (Non-Heme)
- JIZ - Atomic Absorption, Iron (Non-Heme)
- JJA - Radio-Labeled Iron Method, Iron (Non-Heme)

Devices classified under 21 CFR 862.1415 Iron-binding capacity test system, which includes the following product codes:

- JMO - Ferrozine (Colorimetric) Iron Binding Capacity
- JQD - Resin, Ion-Exchange, Thioglycolic Acid, Colorimetry, Iron Binding Capacity
- JQE - Resin, Ion-Exchange, Ascorbic Acid, Colorimetry, Iron Binding Capacity
- JQF - Bathophenanthroline, Iron Binding Capacity
- JQG - Radiometric, Fe59, Iron Binding Capacity

Devices classified under 21 CFR 862.1580 Phosphorous (inorganic) test system, which includes the following product code:

- CEO - Phosphomolybdate (Colorimetric), Inorganic Phosphorus

Devices classified under 21 CFR 862.1775 Uric acid test system, which includes the following product codes:

- CDH - Acid, Uric, Phosphotungstate Reduction
- CDO - Acid, Uric, Uricase (U.V.)
- JHA - Acid, Uric, Uricase (Gasometric)
- JHC - Acid, Uric, Uricase (Oxygen Rate)
- KNK - Acid, Uric, Uricase (Colorimetric)
- LFQ - Acid, Uric, Acid Reduction Of Ferric Ion

Devices classified under 21 CFR 862.3050 Breath - alcohol test system, which includes the following product code:

- DJZ - Devices, Breath Trapping, Alcohol

Devices classified under 21 CFR 862.3220 Carbon monoxide test system, which includes the following product codes:

- JKS - Spectral Absorb. Curve, Oxyhemoglobin, Carboxyhemoglobin, Carbon-Monoxide
- JKT - Gas Chromatograph, Carbon-Monoxide
- MKU - Enzyme Immunoassay, Nicotine And Nicotine Metabolites
- MRS - Test System, Nicotine, Cotinine, Metabolites

Devices classified under 21 CFR 862.3240 Cholinesterase test system, which includes the following product codes:

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DIG - Cholinesterase Test Paper
DIH - Colorimetry, Cholinesterase
DLI - Acetylcholine Chloride, Specific Reagent For Pseudo Cholinesterase
DMR - Solution, M-Nitrophenol, Specific Reagent For Cholinesterase
DOH - Electrometry, Cholinesterase

Devices classified under 21 CFR 862.1020 Acid phosphatase (total or prostatic) test system, which includes the following product codes:

CJN - Acid Phosphatase, Nitrophenylphosphate
CJR - Acid Phosphatase, Thymol Blue Monophosphate
CJX - Acid Phosphatase, Disodium Phenylphosphate
CKB - Acid Phosphatase, Naphthyl Phosphate
CKE - Acid Phosphatase, Thymolphthale Inmonophosphate
CKH - Acid Phosphatase, Beta Glycerophosphate
JFH - Acid Phosphatase (Prostatic), Tartrate Inhibited

Devices classified under 21 CFR 862.1090 Angiotensin converting enzyme (A.C.E) test system, which includes the following product code:

KQN - Radioassay, Angiotensin Converting Enzyme

Devices classified under 21 CFR 862.1100 Aspartate amino transferase (AST/SGOT) test system, which includes the following product codes:

CIF - Vanillin Pyruvate, Ast/Sgot
CIQ - Diazo, Ast/Sgot
CIS - Hydrazone Colorimetry, Ast/Sgot
CIT - Nadh Oxidation/Nad Reduction, Ast/Sgot

Devices classified under 21 CFR 862.1445 Lactate dehydrogenase isoenzymes test system, which includes the following product codes:

CEX - Chromatographic Separation, Lactate Dehydrogenase Isoenzymes
CFE - Electrophoretic, Lactate Dehydrogenase Isoenzymes
JGF - Differential Rate Kinetic Method, Lactate Dehydrogenase Isoenzymes

Devices classified under 21 CFR 862.1509 Methylmalonic acid (non-quantitative) test system, which includes the following product code:

LPT - System, Test, Urinary Methylmalonic Acid

Devices classified under 21 CFR 862.1685 Thyroxine-binding globulin test system, which includes the following product code:

CEE - Radioimmunoassay, Thyroxine-Binding Globulin

Devices classified under 21 CFR 862.1700 Total thyroxine test system, which includes the following product codes:

CDX - Radioimmunoassay, Total Thyroxine
KLI - Enzyme Immunoassay, Non-Radiolabeled, Total Thyroxine

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Hematology Devices

Devices classified under 21 CFR 864.6650 - Platelet adhesion test, which includes the following product code:

JBZ- Study, Platelet Adhesive

Devices classified under 21 CFR 864.7275 - Euglobulin lysis time tests, which includes the following product code:

JBO - Test, Euglobulin Lysis

Devices classified under 21 CFR 864.7300 - Fibrin monomer paracoagulation test, which includes the following product codes:

JBN - Fibrin Monomer Paracoagulation

Devices classified under 21 CFR 864.7375 - Glutathione reductase assay, which includes the following product codes:

GII - Glutathione, Red-Cell

JMH - Fluorescence, Visual Observation (Qual., U.V.), Glutathione Reductase

KQF - Assay, Glutathione Reductase

Devices classified under 21 CFR 864.7720 Prothrombin consumption test, which includes the following product code:

GGQ - Test, Prothrombin Consumption

Devices classified under 21 CFR 864.7735 - Prothrombin-proconvertin test and thrombotest, which includes the following product code:

JPF- Prothrombin-Proconvertin And Thrombotest

Immunology and Microbiology Devices

Devices classified under 21 CFR 866.5470 - Hemoglobin immunological test system, which includes the following product code:

DAM - Hemoglobin, Chain Specific, Antigen, Antiserum, Control

Radiology Devices

Devices classified under 21 CFR 892.1610, Diagnostic x-ray beam-limiting device, which includes the following product codes:

IZS – Aperature, Radiographic

IZW – Collimator, Automatic, Radiographic

IZX – Collimator, Manual, Radiographic

IZT –Cone, Radiographic

KPW – Device, Beam Limiting, X-Ray, Diagnostic

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Devices classified under 21 CFR 892.1670, Spot-film device, which includes the following product code:

IXL – Device, Spot-Film

Devices classified under 21 CFR 892.1850, Radiographic film cassette, which includes the following product code:

IXA – Cassette, Radiographic Film

Devices classified under 21 CFR 892.1860, Radiographic film/cassette changer, which includes the following product code:

KPX – Changer, Radiographic Film/Cassette

Devices classified under 21 CFR 892.1870, Radiographic film/cassette changer programmer, which includes the following product code:

IZP – Programmer, Changer, Film/Cassette, Radiographic

Devices classified under 21 CFR 892.1900, Automatic radiographic film processor, which includes the following product codes:

EGT – Controller, Temperature, Radiographic

EGW – Dryer, Film, Radiographic

IXX – Processor, Cine film

IXW – Processor, Radiographic-Film, Automatic

EGY – Processor, Radiographic-Film, Automatic, Dental

Devices classified under 21 CFR 892.2030, Medical image digitizer, which includes the following product codes:

LMA – Digitizer, Image, Radiological

NFH – Digitizer, Images, Ophthalmic

Devices classified under 21 CFR 892.2040, Medical image hardcopy device, which includes the following product codes:

LMC – Camera, Multi Format, Radiological

NFI – Device, Hardcopy, Images, Ophthalmic

Devices classified under 21 CFR 892.1820 Pneumoencephalographic chair, which includes the following product codes:

HBK – Chair, Pneumocephalographic