Manchester, NH, KMHT, RNAV (GPS) Y
RWY 17, Amdt 1D
Pittstown, NJ, Alexandria, Takeoff
Minimums and Obstacle DP, Amdt 3
Owyhee, NV, 10U, RNAV (GPS) RWY 5, Orig
Owyhee, NV, Owyhee, Takeoff Minimums
and Obstacle DP, Orig
New York, NY, KLGA, COPTER ILS OR LOC
RWY 13, Amdt 1
Saranac Lake, NY, KSLK, ILS OR LOC RWY
23, Amdt 11
Saranac Lake, NY, KSLK, RNAV (GPS) RWY
23, Amdt 1
Athens/Albany, OH, KUNI, NDB RWY 25,
Amdt 9D
Dayton, OH, 3I7, RNAV (GPS)-A, Orig
Dayton, OH, 3I7, VOR OR GPS RWY 21,
Amdt 3B, CANCELLED
Gallipolis, OH, KGAS, RNAV (GPS) RWY 23,
Amdt 1
Springfield, OH, KSGH, NDB RWY 24, Amdt
17, CANCELLED
Wilmington, OH, KILN, ILS OR LOC RWY
4L, Amdt 4E
Wilmington, OH, KILN, ILS OR LOC RWY
4R, Orig-D
Wilmington, OH, KILN, ILS OR LOC RWY
22L, ILS RWY 22L (SA CAT I), ILS RWY
22L (CAT II), Orig-D
Wilmington, OH, KILN, ILS OR LOC RWY
22R, ILS RWY 22R (SA CAT I), ILS RWY
22R (CAT II), ILS RWY 22R (CAT III),
Amdt 6A
Wilmington, OH, KILN, RNAV (GPS) RWY
4L, Orig-D
Hinton, OK, 2O8, RNAV (GPS) RWY 18,
Amdt 1C
Hinton, OK, 2O8, RNAV (GPS) RWY 36,
Amdt 1C
Hinton, OK, Hinton Muni, Takeoff
Minimums and Obstacle DP, Orig-A
Abilene, TX, KABI, RNAV (GPS) RWY 22,
Orig-B. CANCELLED
Abilene, TX, Abilene Rgnl, Takeoff
Minimums and Obstacle DP, Amdt 4A
Austin, TX, KEDC, RNAV (GPS) RWY 31,
Amdt 1A
Barre/Montpelier, VT, KMPV, RNAV (GPS)
RWY 35, Amdt 2
Seattle, WA, KSEA, ILS OR LOC RWY 16L,
ILS RWY 16L (SA CAT I), ILS RWY 16L
(CAT II), ILS RWY 16L (CAT III), Amdt 8A
Green Bay, WI, KGRB, RNAV (GPS) RWY 6,
Amdt 2B
Green Bay, WI, KGRB, RNAV (GPS) RWY 18,
Amdt 1C
Green Bay, WI, KGRB, RNAV (GPS) RWY 36,
Amdt 3B
Ravenswood, WV, I18, RNAV (GPS) RWY 4,
Orig-B
Sheridan, WY, KSHR, RNAV (GPS) RWY 33,
Amdt 1A
    RESCINDED: On March 24, 2021 (86 FR
15583), the FAA published an Amendment
in Docket No. 31359 Amdt No. 3947, to Part
97 of the Federal Aviation Regulations under
section 97.23 and 97.25. The following
entries for Beverly, MA, effective April 22,
2021, are hereby rescinded in their entirety:
Beverly, MA, KBVY, LOC RWY 16, Amdt 8
Beverly, MA, Beverly Rgnl, VOR RWY 16,
Amdt 5E, CANCELLED

[FR Doc. 2021–07853 Filed 4–16–21; 8:45 am]

BILLING CODE 4910–13–P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

**21 CFR Parts 862, 866, 880, 884 and
892**

[Docket No. FDA–2018–N–1440]

RIN 0910–AH67

**Medical Devices; Medical Device
Classification Regulations To Conform
to Medical Software Provisions in the
21st Century Cures Act**

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug
Administration (FDA, Agency, or we) is
amending certain classification
regulations to reflect changes to the
Federal Food, Drug, and Cosmetic Act
(FD&C Act) made by the 21st Century
Cures Act (the Cures Act). The Cures
Act amended the definition of a device
in the FD&C Act to exclude certain
software functions. FDA is taking this
action so that its regulations conform to
the medical software provisions in the
Cures Act.

DATES: This rule is effective on April 19,
2021.

FOR FURTHER INFORMATION CONTACT:
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Radiological Health, Food and Drug
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Bakul.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

    On December 13, 2016, the Cures Act
was enacted (Pub. L. 114–255). The
Cures Act amended the FD&C Act to
include descriptions of software
functions that are excluded from the
definition of device in the FD&C Act.
The Cures Act amended the FD&C Act
to state that the term device does not
include the software functions excluded
pursuant to section 520(o)(1) of the
FD&C Act.

    Among the software functions
excluded from the definition of device
by this provision, most relevant to this
rule are the software functions intended
to transfer, store, convert formats, or
display clinical laboratory test or other
device data, results, and findings and
that do not interpret or analyze such
clinical laboratory test or other device
data, results, and findings. Because the
provision only excludes certain software
functions from the device definition, the
regulatory status of device hardware
remains unchanged. With this final rule,
FDA is amending the ''identification''
description of eight classification
regulations so that the regulations no
longer include software functions that
the Cures Act excluded from the device
definition in the FD&C Act. In other
words, in this action, FDA is amending
eight classification regulations so that
the regulations conform to the medical
software provisions of the Cures Act and
reflect FDA's current statutory
authority.

*B. Summary of the Major Provisions of
the Final Rule*

    This rule updates eight classification
regulations by amending these
regulations to exclude software
functions that no longer fall within the
device definition under 201(h) of the
FD&C Act. Specifically, FDA is
amending the following classification
regulations:

    • Amend the calculator/data
processing module for clinical use
''identification'' description to remove
non-device software functions that
maintain and retrieve laboratory data;

    • amend the continuous glucose
monitor (CGM) secondary display
''identification'' description to remove
receive and display software functions,
and amend the title of the CGM
secondary display regulation to

''Continuous Glucose Monitor (CGM) Secondary Alarm System;''

• amend the automated indirect immunofluorescence microscope and software-assisted system device ''identification'' description by replacing the first use of the word ''software'' with ''device'' because both hardware and software functions that use fluorescent signal acquisition and processing software, data storage, and transferring mechanisms, or assay specific algorithms to interpret or analyze results, are devices;

• amend the medical device data systems (MDDS) ''identification'' description to remove non-device software functions intended for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results;

• amend the home uterine activity monitor (HUAM) ''identification'' description to remove non-device software functions intended for

transmitting, receiving, and displaying data;

• amend medical image storage device ''identification'' description to remove non-device software functions intended for storing and retrieving so that a medical image storage device is a hardware device that provides electronic storage and retrieval functions for medical images;

• amend medical image communications device ''identification'' description to include software functions intended for medical image processing and manipulation; and

• amend picture archiving and communications system ''identification'' description to remove non-device software functions intended for storing and displaying medical images, revise the ''identification'' description to clarify that the regulation includes software and hardware functions intended for medical image management and processing, and revise

the title of the classification regulation to ''Medical Image Management and Processing System.''

This final rule does not change the classification of the device types for which FDA is amending the title and/or identification statements. This rule will ensure that the specific classification regulations conform to changes the Cures Act made to the FD&C Act and reflect current FDA statutory authority.

C. Legal Authority

This final rule is being issued under sections 201(h), 520(o), and 701 of the FD&C Act (21 U.S.C. 321, 360j, and 371) and the device and general administrative provisions of the FD&C Act sections 501, 510, 513, 515, 520, 522, and 701 (21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* and 371).

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation or acronym	What it means
510(k)	Premarket Notification.
APA	Administrative Procedure Act.
CFR	Code of Federal Regulations.
CGM	Continuous Glucose Monitor.
Cures Act	21st Century Cures Act.
E.O	Executive Order.
FDA or the Agency	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
HUAM	Home Uterine Activity Monitor.
IMACS	Image Management and Communications Systems.
MDDS	Medical Device Data System.
PACS	Picture Archiving and Communications System.
U.S.C	United States Code.

III. Background

On December 13, 2016, the Cures Act was enacted. The Cures Act amended, among other things, FDA's authority to regulate medical software, including certain clinical decision support software. The provision of the Cures Act entitled ''Clarifying Medical Software Regulation,'' amended section 520 of the FD&C Act by adding subsection (o), which describes specific software functions that are excluded from the definition of device in the FD&C Act (section 201(h) of FD&C Act).

Section 520(o)(1) of the FD&C Act excludes from the definition of device software functions that are intended for:

1. Administrative support of a healthcare facility (section 520(o)(1)(A));

2. Maintaining or encouraging a healthy lifestyle and unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (section 520(o)(1)(B));

3. Serving as electronic patient records, including patient-provided

information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as such records were created, stored, transferred, or reviewed by healthcare professionals or by individuals working under supervision of such professionals; such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)); and such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (section 520(o)(1)(C)); or

4. Transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a healthcare professional with respect to such data and results, unless such function is intended to interpret or analyze clinical

laboratory test or other device data, results, or findings (section 520(o)(1)(D)); or

5. Unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—(section 520(o)(1)(E));

a. Displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) (section 520(o)(1)(E)(i));

b. Supporting or providing recommendations to a healthcare professional about prevention, diagnosis, or treatment of a disease or condition (section 520(o)(1)(E)(ii)); and

c. Enabling such healthcare professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such healthcare professional rely primarily on any of

such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient (section 520(o)(1)(E)(iii)).

The Cures Act also provides that a software function described in section 520(o)(1)(C), (D), or (E) of the FD&C Act will not be excluded from the device definition under section 201(h) of the FD&C Act if FDA makes a finding that the software function would be reasonably likely to have serious adverse health consequences and certain substantive and procedural criteria are met (section 520(o)(3) of the FD&C Act). Also, nothing in section 520(o)(1) should exclude regulated software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans (section 520(o)(4) of the FD&C Act).

A device, as defined in section 201(h) of the FD&C Act, may be comprised of one or more functions that are subject to FDA oversight. FDA defines the term "function" as a distinct purpose of a product, which could be the intended use or a subset of the intended use of the product and is not synonymous with the term "device." For example, a device with an intended use to analyze data has one function: Analysis. A device with an intended use to store, transfer, and analyze data has three functions: (1) Storage, (2) transfer, and (3) analysis. Devices with "multiple functions" may contain functions that are software functions excluded from the device definition as described in section 520(o) of the FD&C Act.

FDA is issuing this final rule because the FD&C Act was amended by the Cures Act to remove certain software functions from the device definition, including software functions that are solely intended to transfer, store, convert formats, or display medical device data and results, including medical images or other clinical information, unless such functions are intended to interpret or analyze clinical laboratory test or other device data, results, and findings (sections 201(h) and 520(o)(1)(D) of the FD&C Act).

FDA is making its regulations consistent with the FD&C Act as amended by the Cures Act by amending the "identification" descriptions in eight regulations so that the descriptions do not include software functions that no longer fall within the definition of a

device. The Agency has conducted a detailed review of all device classification regulations to determine whether the classification regulations contain software functions identified under section 520(o)(1)(A)–(E) of the FD&C Act (see 21 CFR parts 862–892), and therefore should be amended to reflect changes the Cures Act made to FDA's device statutory authority. As a result of this review, FDA identified eight classification regulations to amend (see Table 1 below).

Because of changes made to the FD&C Act by the Cures Act, the "identification" description of certain classification regulations that predated the Cures Act are no longer consistent with the FD&C Act. FDA finds good cause for issuing this amendment as a final rule without notice and comment because this rule only updates the "identification" description of those classification regulations so they reflect changes made to the FD&C Act by the Cures Act (see section 520(o)(1) of the FD&C Act) (5 U.S.C. 553(b)(3)(B)). In addition, FDA also finds good cause for this amendment to become effective on the date of publication of this action. The Administrative Procedure Act (APA) allows an effective date less than 30 days after publication as "provided by the agency for good cause found and published with the rule" (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because these amendments reflect the state of the law in section 520(o)(1) of the FD&C Act as amended by section 3060 of the Cures Act. This rule does not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for these amendments to become effective on the date of publication of this action.

IV. Legal Authority

This final rule is being issued under sections 201(h), 520(o), and 701 of the FD&C Act and the device and general administrative provisions of the FD&C Act sections 501, 510, 513, 515, 520, 522, and 701.

V. Description of the Final Rule

A. Scope

FDA is amending the "identification" description in eight classification

regulations, so that they no longer include software functions that are excluded from the device definition by section 520(o)(1) of the FD&C Act and thus are not subject to FDA's device statutory authority. Among the software functions excluded from the definition of device in the FD&C Act, most relevant to this rule are the software functions excluded by section 520(o)(1)(D) of the FD&C Act. This provision excludes software functions that are solely intended to transfer, store, convert formats, or display, unless such functions are intended to interpret or analyze clinical laboratory test or other device data, results, and findings. This includes functions that are intended for data retrieval, receipt, or transmission because these are forms of information "transfer," and functions that are intended for data maintenance, which is a form of "storage" (section 520(o)(1)(D) of the FD&C Act; see also FDA guidance "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" (Ref. 1)). However, software functions that analyze or interpret medical device data in addition to transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results remain subject to FDA's regulatory oversight, unless they fall within section 520(o)(1)(E) of the FD&C Act, which excludes certain clinical decision support software functions from the device definition.

Section 520(o)(1) of the FD&C Act describes software functions, not hardware functions, that are excluded from the definition of a device. Therefore, device hardware that is specifically intended to transfer, store, convert formats, and display medical device data and results (such as electrical hardware, magnetic and optical discs, physical communications medium, etc.) remains a device.

In Table 1, we list the regulations that FDA is amending to conform the "identification" description with the device definition under the FD&C Act. The amendments to the "identification" description of these regulations do not affect the classification of the devices in this final rule (*i.e.,* the device types remain class I, class II, etc.).

TABLE 1—CLASSIFICATION REGULATIONS AMENDMENTS

Classification regulation (21 CFR)	Device type (existing product code(s))
862.2100	Calculator/Data Processing Module for Clinical Use (JQP, NVV).

TABLE 1—CLASSIFICATION REGULATIONS AMENDMENTS—Continued

Classification regulation (21 CFR)	Device type (existing product code(s))
862.1350	Continuous Glucose Monitor Secondary Display (PJT, PKU).
866.4750	Automated Indirect Immunofluorescence Microscope and Software-Assisted System (PIV).
880.6310	Medical Device Data System (OUG).
884.2730	Home Uterine Activity Monitor (LQK, MOH).
892.2010	Medical Image Storage Device (LMB, NFF).
892.2020	Medical Image Communications Device (NFG, LMD).
892.2050	Picture Archiving and Communications System (QIH, OMJ, NWE, PGY, OEB, QKB, PZO, NFJ, LLZ).

B. Calculator/Data Processing Module for Clinical Use

A calculator/data processing module for clinical use is an electronic device intended to store, retrieve, and process laboratory data (21 CFR 862.2100). Because ''storing and retrieving data'' are software functions that no longer fall within the definition of a device, FDA is amending the classification regulation to remove the language ''store, retrieve, and'' so that the regulation will state: ''a calculator/data processing module for clinical use is an electronic device intended to process laboratory data.''

C. Continuous Glucose Monitor Secondary Display

A CGM secondary display is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data § 862.1350 (21 CFR 862.1350). The identification further describes that the primary display device, which is not a part of the CGM secondary display, directly receives the glucose data (for example, it communicates directly with transmitter) from the continuous glucose meter, which is not a part of the continuous glucose monitor secondary display, and is the primary means of viewing the continuous glucose monitor data and alerting the patient to a low or high glucose value. A continuous glucose monitor secondary display can be used by caregivers of people with diabetes to monitor a person's continuous glucose monitoring data.

The intended use of the device, as explained in FDA's 2015 Dexcom Share Direct Secondary Displays (DEN140038) order, includes the functions to receive and display medical device data (*i.e.,* real-time glucose values and glucose trend information), in addition to functions to receive and deliver notifications and alarms. Because of changes made to the FD&C Act by the Cures Act, receiving and displaying device data software functions are no longer device functions. To make this regulation consistent with the FD&C Act, therefore, FDA is amending the title of the classification in § 862.1350 to

''continuous glucose monitor secondary alarm system'' and is amending the ''identification'' description to state that ''a continuous glucose monitor (CGM) secondary alarm system is identified as a device intended to be used as a secondary alarm for a CGM to enable immediate awareness for potential clinical intervention to help assure patient safety.'' With these amendments, the regulation no longer includes software functions excluded by the Cures Act, *i.e.,* functions to receive and display medical device data.

D. Automated Indirect Immunofluorescence Microscope and Software-Assisted System

An automated indirect immunofluorescence microscope and software-assisted system is a device that acquires, analyzes, stores, and displays digital images of indirect immunofluorescent slides (21 CFR 866.4750). FDA is replacing the first occurrence of the word ''software'' with ''device'' in the identification section, so that the identification will state that the device may use fluorescent signal acquisition and processing software, data storage and transferring mechanisms, or assay specific algorithms to suggest results. Because some of the software functions included in the regulation remain within the device definition (*e.g.,* assay specific algorithms to suggest results), the ''identification'' description will not be limited to hardware functions only. Instead, FDA is using the term ''device,'' which includes software functions that continue to fall within the device definition and hardware functions.

E. Medical Device Data System

An MDDS is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices: (1) The electronic transfer of medical device data; (2) the electronic storage of medical device data; (3) the electronic conversion of medical device data from one format to another format in accordance with a preset

specification; or (4) the electronic display of medical device data (§ 880.6310 (21 CFR 880.6310)). An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. Each MDDS function ((1)–(4)) describes a software function that is excluded from the device definition under section 520(o)(1)(D) of the FD&C Act. Thus, FDA is amending the regulation to state that only hardware that performs these functions remain within the definition of devices by adding the term ''hardware'' to the ''identification'' description so that the regulation (§ 880.6310(a)(1)) states that an MDDS is a ''hardware device that is intended to provide one or more of the following uses . . .''.

In addition, FDA is amending § 880.6310(a)(2) to remove the term ''software,'' because the software functions described in the identification of § 880.6310(a)(2) no longer fall within the definition of a device. Further, FDA is removing the phrase ''a communications protocol'' from § 880.6310(a)(2), because the term ''communications protocol'' refers to software functions associated with the transfer of data, and this function does not fall within the definition of a device. FDA is also amending the identification of § 880.6310(a)(2) to include the term ''hardware,'' such that the ''identification'' description states that MDDS ''does not include hardware devices intended to be used in connection with active patient monitoring.'' FDA is revising this identification because hardware devices for active patient monitoring are classified under other regulations for software- and hardware-based devices, and are not included in this regulation. The identification of § 880.6310(a)(2) will be amended to include the following: ''Hardware devices for active patient monitoring are classified under other regulations and are not included in this regulation.''

F. Home Uterine Activity Monitor

A HUAM is an electronic system for at home antepartum measurement of uterine contractions, data transmission by telephone to a clinical setting, and for receipt and display of the uterine contraction data at the clinic (21 CFR 884.2730). The HUAM system comprises a tocotransducer, an at-home recorder, a modem, and a computer and monitor that receive, process, and display data. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor. The identification in the classification regulation for this device includes software functions intended to transmit, receive, and display data, which no longer fall within the statutory definition of a device. Therefore, FDA is removing these software functions from the ''identification'' description in this classification regulation.

G. Medical Image Storage Device

A medical image storage device is a device that provides electronic storage and retrieval functions for medical images and may employ software, electronic, or electrical hardware such as magnetic and optical discs, magnetic tape, and digital memory (§ 892.2010 (21 CFR 892.2010)). Medical image storage includes software functions, specifically storage and retrieval functions, which are excluded from the device definition by section 520(o)(1)(D) of the FD&C Act. Thus, FDA is amending the regulation to state that only hardware that performs these functions remains within the device definition so that the regulation (§ 892.2010(a)(1)) states that a medical image storage device is a ''hardware device that is intended to provide for the electronic storage and retrieval functions for medical images.''

H. Medical Image Communications Device

A medical image communications device provides electronic transfer of medical image data between medical devices (21 CFR 892.2020). The device may include a physical communications medium, modems, or interfaces. In reviewing this classification regulation, FDA has determined that products with specific software functions for medical image processing and manipulation should be mentioned in the ''identification'' description of the classification regulation because such functions have always been included in the regulation and are not excluded under section 520(o)(1)(D) of the FD&C Act. Therefore, FDA is amending this regulation to include the following

clarifying language to the ''identification'' description: ''It may provide simple image review software functionality for medical image processing and manipulation, such as grayscale window and level, zoom and pan, user delineated geometric measurements, compression, or user added image annotations. The device does not perform advanced image processing or complex quantitative functions. This does not include electronic transfer of medical image software functions.''

I. Picture Archiving and Communications System

The Picture Archiving and Communications Systems (PACS) device includes both software and hardware image storage and display functions and software image processing functions (21 CFR 892.2050). FDA has determined that software functions in the PACS classification regulation for storage and display of medical images no longer fall within the definition of a device under section 520(o)(1)(D) of the FD&C Act. However, FDA recognizes that some software functions in the PACS regulation, which are for complex image processing, including those for image manipulation, enhancement, or quantification, remain device functions. Therefore, FDA is amending this regulation to change the title of the classification regulation from ''Picture Archiving and Communications Systems'' to ''Medical Image Management and Processing System'' and is amending the ''identification'' description to exclude software functions for the ''storage and display'' of medical images. In addition, the amendment to the PACS classification regulation clarifies specific functions and the device's intended use with examples in the ''identification'' description.

VI. Effective Date

This final rule is effective on the date of publication in the **Federal Register**.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under E.O. 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). E.O.s 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

Because this final rule merely amends certain classification regulations to remove provisions that are now obsolete in order to conform to the medical software provisions in the Cures Act, it does not impose any additional regulatory burdens. Therefore, we believe that this final rule is not economically significant and not a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this regulation does not change requirements, and amends certain classification regulations to conform to the medical software provisions in the Cures Act, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

Because this direct final rule does not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(i) and 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

We have analyzed this rule in accordance with the principles set forth in E.O. 13132. We have determined that this rule does not contain policies that

have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the E.O. and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in E.O. 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the E.O. and, consequently, a tribal summary impact statement is not required.

XII. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Guidance, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act, available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act.*

List of Subjects

21 CFR Part 862

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 880

Medical devices.

21 CFR Part 884

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, and X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR parts 862, 866, 880, 884, and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Amend § 862.1350 by revising the section heading and paragraph (a) to read as follows:

§ 862.1350 Continuous glucose monitor secondary alarm system.

(a) *Identification.* A continuous glucose monitor (CGM) secondary alarm system is identified as a device intended to be used as a secondary alarm for a CGM to enable immediate awareness for potential clinical intervention to help assure patient safety.

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■ 3. Amend § 862.2100 by revising paragraph (a) to read as follows:

§ 862.2100 Calculator/data processing module for clinical use.

(a) *Identification.* A calculator/data processing module for clinical use is an electronic device intended to process laboratory data.

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PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 4. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 5. Amend § 866.4750 by revising paragraph (a) to read as follows:

§ 866.4750 Automated indirect immunofluorescence microscope and software-assisted system.

(a) *Identification.* An automated indirect immunofluorescence microscope and software assisted system is a device that acquires, analyzes, stores, and displays digital images of indirect immunofluorescent slides. It is intended to be used as an aid in the determination of antibody status in clinical samples. The device may include a fluorescence microscope with light source, a motorized microscope stage, dedicated instrument controls, a camera, a computer, a sample processor, or other hardware components. The device may use fluorescent signal acquisition and processing software, data storage and transferring mechanisms, or assay specific algorithms to suggest results. A trained operator must confirm results generated with the device.

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PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 6. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 7. Amend § 880.6310 by revising paragraph (a) to read as follows:

§ 880.6310 Medical device data system.

(a) *Identification.* (1) A medical device data system (MDDS) is a hardware device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, and interfaces. This identification does not include hardware devices intended to be used in connection with active patient monitoring. Hardware devices for active patient monitoring are classified under other regulations and are not included in this regulation.

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PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 8. The authority citation for part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 9. Amend § 884.2730 by revising paragraph (a) to read as follows:

§ 884.2730 Home uterine activity monitor.

(a) *Identification.* A home uterine activity monitor (HUAM) is an electronic system for at home antepartum measurement of uterine contractions. The HUAM system comprises a tocotransducer and an at-home recorder. This device is intended for use in women with a previous preterm delivery to aid in the detection of preterm labor.

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PART 892—RADIOLOGY DEVICES

■ 10. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 11. Amend § 892.2010 by revising paragraph (a) to read as follows:

§ 892.2010 Medical image storage device.

(a) *Identification:* A medical image storage device is a hardware device that provides electronic storage and retrieval functions for medical images. Examples include electronic hardware devices employing magnetic and optical discs, magnetic tapes, and digital memory.

* * * * *

■ 12. Amend § 892.2020 by revising paragraph (a) to read as follows:

§ 892.2020 Medical image communications device.

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices. It may include a physical communications medium, modems, and interfaces. It may provide simple image review software functionality for medical image processing and manipulation, such as grayscale window and level, zoom and pan, user delineated geometric measurements, compression, or user added image annotations. The device does not perform advanced image processing or complex quantitative functions. This does not include electronic transfer of medical image software functions.

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■ 13. Amend § 892.2050 by revising the section heading and paragraph (a) to read as follows:

§ 892.2050 Medical image management and processing system.

(a) *Identification.* A medical image management and processing system is a device that provides one or more capabilities relating to the review and digital processing of medical images for the purposes of interpretation by a trained practitioner of disease detection, diagnosis, or patient management. The software components may provide advanced or complex image processing functions for image manipulation, enhancement, or quantification that are intended for use in the interpretation and analysis of medical images. Advanced image manipulation functions may include image segmentation, multimodality image registration, or 3D visualization. Complex quantitative functions may

include semi-automated measurements or time-series measurements.

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Dated: April 8, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: April 13, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–07860 Filed 4–16–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–665]

Schedules of Controlled Substances: Removal of Samidorphan From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the Drug Enforcement Administration removes samidorphan (3-carboxamido-4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, samidorphan was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle samidorphan.

DATES: Effective April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Terrence L. Boos, Drug & Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Legal Authority

Under the Controlled Substances Act (CSA), each controlled substance is classified into one of five schedules

based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c) and the current list of scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(2), the Attorney General may, by rule, ''remove any drug or other substance from the schedules if he finds that the drug or other substance does not meet the requirements for inclusion in any schedule.'' The Attorney General has delegated scheduling authority under 21 U.S.C. 811 to the Acting Administrator of the Drug Enforcement Administration (DEA). 28 CFR 0.100.

The CSA provides that proceedings for the issuance, amendment, or repeal of the scheduling of any drug or other substance may be initiated by the Attorney General on the petition of any interested party. 21 U.S.C. 811(a)(3). This action was initiated by one petition to remove samidorphan from the list of scheduled controlled substances of the CSA, and is supported by, *inter alia,* a recommendation from the Assistant Secretary of the HHS and an evaluation of all relevant data by DEA. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle or propose to handle samidorphan.

Background

Samidorphan (3-carboxamido-4-hydroxy naltrexone), is a chemical entity that is structurally similar to naltrexone, a mu (μ)-opioid receptor antagonist. Samidorphan (other developmental code names: RDC–0313 or ALKS 33) is a mu-opioid receptor antagonist with a weak partial agonist activity at the kappa- and delta-opioid receptors. According to HHS, products containing samidorphan are currently being developed for medical use. Samidorphan is currently controlled in schedule II of the CSA, as defined in 21 CFR 1308.12(b)(l), because it can be derived from opium alkaloids. On April 14, 2014, DEA received a petition to initiate proceedings to amend 21 CFR 1308.12(b)(1) so as to decontrol samidorphan from schedule II of the CSA. The petition complied with the requirements of 21 CFR 1308.43(b) and was accepted for filing. The petitioner contended that samidorphan has been characterized as an opioid receptor