



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA-2017-N-1141]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Continuous Glucose Monitor Secondary Display

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the continuous glucose monitor secondary display into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the continuous glucose monitor secondary display's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on January 23, 2015.

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SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, also known as De Novo classification, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of

substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device.

On December 15, 2014, Dexcom Inc., submitted a request for classification of the Dexcom Share Direct Secondary Displays under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on January 23, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.1350.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a continuous glucose monitor secondary display will need to comply with the special controls named in this final administrative order. A De Novo classification decreases regulatory burdens. When FDA classifies a device type as class I or II via the De Novo pathway, other manufacturers do not have to submit a De Novo request or PMA in order to market the same type of device, unless the device has a new intended use or technological characteristics that raise different questions of safety or effectiveness. Instead, manufacturers can use the less burdensome pathway of 510(k), when necessary, to market their device, and the device that was the subject of the original De Novo classification can serve as a predicate device for additional 510(k)s from other manufacturers.

The device is assigned the generic name continuous glucose monitor secondary display, and it is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data. The primary display device, which is not a part of the continuous glucose monitor 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. A device is not a continuous glucose monitor secondary display if the data from the primary display device is modified (for example, predicting future glucose values) or the patient can use the secondary display in lieu of a primary display device (for example, the primary display device is blinded or the primary display does not have to be near the person wearing the sensor and transmitter).

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks:

Table 1.--Continuous Glucose Monitor Secondary Display Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Incorrect glucose value reported on the secondary display or glucose value missed due to cybersecurity breach.	21 CFR 862.1350(b)(1)
Treatment recommendations are made based on data presented by secondary display device.	21 CFR 862.1350(b)(2)
Individual with diabetes becomes overly reliant on “followers” for monitoring their glucose levels.	21 CFR 862.1350(b)(3)

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k), if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the continuous glucose monitor secondary display they intend to market.

II. Analysis of Environmental Impact

We have determined under 21 CFR 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.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862--CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for part 862 is revised to read as follows:

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

2. Add § 862.1350 to subpart B to read as follows:

§ 862.1350 Continuous glucose monitor secondary display.

(a) Identification. A continuous glucose monitor secondary display is identified as a device intended to be used for passive real-time monitoring of continuous glucose monitoring data. It must not be capable of serving as a stand-alone primary display device. The primary display device, which is not a part of the continuous glucose monitor 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. A device is not a continuous glucose monitor secondary display if the data from the primary display device is modified (for example, predicting future glucose values) or the patient can use the secondary display in lieu of a primary display device (for example, the primary display device is blinded or the primary display does not have to be near the person wearing the sensor and transmitter).

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Devices being marketed must include appropriate measures to protect against unauthorized access to data and unauthorized modification of data.

(2) The labeling must prominently and conspicuously display a warning that states "Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system."

(3) The labeling for the device must include a statement that reads "This device is not intended to replace self-monitoring practices as advised by a physician."

Dated: March 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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