generally referred to as postamendments Medical Device Amendments of 1976),
commercial distribution before May 28, (the date of enactment of the
Act (the FD&C Act) (21 U.S.C.
the Federal Food, Drug, and Cosmetic
SUMMARY:
ACTION:
AGENCY:
FDA shall classify the device by written
by section 513(f)(2) of the FD&C Act,
under section 513(f)(2). Under the
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
codifies 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

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
Federal Register

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The collections of information for 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

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

§ 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).

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

<table>
<thead>
<tr>
<th>Identified risks</th>
<th>Mitigation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incorrect glucose value reported on the secondary display or glucose value missed due to cybersecurity breach</td>
<td>21 CFR 862.1350(b)(1).</td>
</tr>
<tr>
<td>Treatment recommendations are made based on data presented by secondary display device</td>
<td>21 CFR 862.1350(b)(2).</td>
</tr>
<tr>
<td>Individual with diabetes becomes overly reliant on “followers” for monitoring their glucose levels</td>
<td>21 CFR 862.1350(b)(3).</td>
</tr>
</tbody>
</table>

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 of the device. 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).