collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; 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 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

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

■ 2. Add § 864.7295 to subpart H to read as follows:

§ 864.7295 Heparin and direct oral factor Xa inhibitor drug test system.

(a) *Identification.* A heparin and direct oral factor Xa inhibitor drug test system is intended for the detection of heparin and direct oral factor Xa inhibitors in human specimens collected from patients taking heparin or direct oral factor Xa inhibitors. This device is intended to aid in the management of therapy in conjunction with other clinical and laboratory findings.

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

(1) Design verification and validation must include the following:

(i) Detailed documentation of analytical device performance studies and results demonstrating acceptable analytical performance with a sufficient number of specimens tested in order to obtain unbiased estimates of analytical performance. This documentation shall include the following as appropriate to the technology, specimen types tested, and intended use of the device:

(A) Studies and results for that demonstrate device precision including repeatability and reproducibility, using quality controls and clinical samples, when appropriate. Precision studies must assess specimens for each indicated drug at concentrations throughout the measuring range of the device including near clinically relevant levels, as appropriate. The study must evaluate different sources of variability including, as appropriate, between-run, between-operator, between-lot, between-instrument, between-day, and between-site;

(B) Studies and results that demonstrate that the device is free from clinically significant interference, from endogenous and exogenous interferents associated with the target population(s), and interferents that are specific for, or related to, the technology or methodology of the device;

(C) Data to demonstrate appropriate specimen stability for the intended sample matrices under the intended conditions for specimen collection, handling, and storage described in the device labeling;

(D) Studies and results that demonstrate the linear range, limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ), as applicable to the technology of the device; and

(E) For any devices intended for use for near patient testing, studies and results that demonstrate the robustness of the device in the hands of the intended user, including the entire testing procedure, pre-analytical specimen processing steps, and results interpretation.

(ii) Detailed documentation of clinical performance testing in which the performance is analyzed relative to a comparator that FDA has determined is appropriate. Specimens must be representative of the intended use population(s) and must cover the full range of the device output and any clinically relevant decision points as appropriate.

(2) The labeling required under § 809.10(b) of this chapter must include:

(i) Identification of any known interferents, including all endogenous, exogenous, technology-specific, and patient population-specific interferents, specific to the test outputs. The information must include the concentration(s) or level(s) of the interferent at which clinically significant interference was found to occur, and the concentration range or levels at which interference was not found to occur;

(ii) A prominent statement that the device is not intended for use in monitoring patients taking heparin or direct oral factor Xa inhibitors; and

(iii) Limiting statements indicating, as applicable:

(A) That the device should only be used in conjunction with information available from clinical evaluations and other diagnostic procedures; and

(B) That the device is not specific to the direct oral factor Xa inhibitor that has been evaluated and may detect the presence of other direct factor Xa inhibitors that have not been evaluated.

Dated: August 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19824 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2024–N–3947]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Open Loop Fluid Therapy Recommender

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the adjunctive open loop fluid therapy recommender into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the adjunctive open loop fluid therapy recommender's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices.

DATES: This order is effective September 5, 2024. The classification was applicable on November 13, 2020.

FOR FURTHER INFORMATION CONTACT: Biniyam Taddese, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2544, Silver Spring, MD 20993–0002, 240–402–6570, *Biniyam.Taddese@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the adjunctive open loop fluid therapy recommender as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains

within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act (see also part 860, subpart D (21 CFR part 860, subpart D)). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 4, 2019, FDA received Edwards Lifesciences' request for De Novo classification of the Acumen Assisted Fluid Management (AFM) Software Feature. 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.

We classify 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 that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on November 13, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 870.5600.[1] We have named the generic type of device adjunctive open loop fluid therapy recommender, and it is identified as a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict a patient's estimated response to fluid therapy. The device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—ADJUNCTIVE OPEN LOOP FLUID THERAPY RECOMMENDER RISKS AND MITIGATION MEASURES

Identified risks to health	Mitigation measures
Delay in monitoring or treatment	Software verification, validation, and hazard analysis; Usability assessment; and Labeling.
Inappropriate or missed treatment due to over-reliance on software recommendation, which is affected by algorithm or software error, or inaccurate input from sensors or users.	Software verification, validation, and hazard analysis; Non-clinical performance testing; Usability assessment; Clinical performance testing; and Labeling.
Fluid overload due to over-reliance on software recommendations, which are affected by algorithm or software error, or inaccurate input from sensors or users.	Software verification, validation, and hazard analysis; Non-clinical performance testing; Usability assessment; Clinical performance testing; and Labeling.

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. For a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to

[1] FDA notes that the **ACTION** caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, the adjunctive open loop fluid therapy recommender is for prescription use only. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met.

III. Analysis of Environmental Impact

The Agency has 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.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations and guidance. 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. 3501–3521). The collections of information in part 860, subpart D, regarding De Novo classification have been approved under OMB control number 0910–0844; the collections of information in 21 CFR part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 870

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 870 is amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for part 870 continues to read as follows:

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

■ 2. Add § 870.5600 to subpart F to read as follows:

§ 870.5600 Adjunctive open loop fluid therapy recommender

(a) *Identification.* The adjunctive open loop fluid therapy recommender is a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict a patient's estimated response to fluid therapy. The device is intended for adjunctive use with other physical vital sign parameters and patient information and is not intended to independently direct therapy.

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

(1) Clinical performance testing under anticipated conditions of use must fulfill the following:

(i) A summary of the clinical performance testing must include the relevant patient demographics, and any statistical techniques used for analyzing the data;

(ii) Subjects must be representative of the intended use population for the device. Any selection criteria or sample limitations must be fully described and justified;

(iii) Testing must demonstrate the recommendation consistency using the expected range of data sources and data quality encountered in the intended patients, users, and environments; and

(iv) Testing must evaluate the relationship between algorithm recommendations, therapeutic actions, and predicted physiological event or status.

(2) A software description and the results of verification and validation testing based on a comprehensive hazard analysis and risk assessment must be provided, including:

(i) A full characterization of the software technical parameters, including algorithms;

(ii) A description of the expected recommendation, accounting for differences in patient condition and environment;

(iii) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) that affect the device's recommendations;

(iv) A characterization of algorithm sensitivity to variations in user inputs;

(v) A characterization of sensor accuracy and performance;

(vi) A description of sensor data quality control measures; and

(vii) Safeguards to reduce the possibility of fluid overload.

(3) A scientific justification for the validity of the algorithm(s) must be provided. This justification must include non-clinical verification and validation of the algorithm calculations and clinical validation using an independent data set.

(4) A human factors and usability engineering assessment must be provided.

(5) Labeling must include:

(i) A description of what the device measures, how the device decides to issue recommendations, and the expected range of frequency of recommendations, while accounting for differences in patient condition and environment;

(ii) Detailed information regarding limitations of the device's algorithm, and key assumptions made when the device issues a recommendation;

(iii) Warnings identifying sensor acquisition factors that may impact measurement results;

(iv) Warnings identifying user errors that affect the device's recommendations;

(v) Detailed information regarding the expected impact of user input errors on the device recommendations;

(vi) Guidance for interpretation of the device's recommendations, including a description that the recommendation is adjunctive to other physical vital sign parameters and patient information;

(vii) Description of the impact of the compatible sensor(s) on the device's performance;

(viii) The expected performance of the device for all intended patients, users, and environments;

(ix) Relevant characteristics of the patients studied in the clinical validation (such as age, gender, race or ethnicity, and patient condition) and a summary of validation results; and

(x) Description of the software safeguards that are in place to prevent fluid overload, and description of any limitation of the software safeguards.

Dated: August 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–19736 Filed 9–4–24; 8:45 am]

BILLING CODE 4164–01–P