(e) An ability to move participants with multiple barriers to employment, including individuals described in § 641.570(b) or § 641.520(a)(2) through (9), into unsubsidized employment;

* * * * *

Subpart E—Services to Participants

■ 5. Amend § 641.520 by revising the section heading and paragraphs (a)(7) and (8) and adding paragraph (a)(9) to read as follows:

§ 641.520 Are there any priorities that grantees and sub-recipients must use in selecting eligible individuals for participation in the Senior Community Service Employment Program?

(a) * * *

(7) Have failed to find employment after using services provided through the one-stop delivery system;

(8) Are homeless or are at risk for homelessness; or

(9) Are formerly incarcerated individuals as defined in § 641.140. (OAA sec. 518(b).)

* * * * *

■ 6. Amend § 641.570 by revising paragraphs (b)(4) and (5) and adding paragraph (b)(6) to read as follows:

§ 641.570 Is there a time limit for participation in the program?

* * * * *

(b) * * *

(4) Live in an area with persistent unemployment and are individuals with severely limited employment prospects;

(5) Have limited English proficiency or low literacy skills; or

(6) Are formerly incarcerated individuals as defined in § 641.140.

* * * * *

Subpart G—Performance Accountability

■ 7. Amend § 641.710 by revising paragraphs (g)(12) and (13) and adding paragraph (g)(14) to read as follows:

§ 641.710 How are the performance measures defined?

* * * * *

(g) * * *

(12) Have failed to find employment after utilizing services provided under title I of the Workforce Innovation and Opportunity Act;

(13) Are homeless or at risk for homelessness; or

(14) Are formerly incarcerated individuals as defined in § 641.140.

Angela Hanks,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2022–02680 Filed 2–11–22; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2021–N–0999]

Medical Devices; Cardiovascular Devices; Classification of the Adjunctive Predictive Cardiovascular Indicator

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the adjunctive predictive cardiovascular indicator 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 predictive cardiovascular indicator'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 February 14, 2022. The classification was applicable on March 16, 2018.

FOR FURTHER INFORMATION CONTACT: Aneesh Deoras, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2564, Silver Spring, MD 20993–0002, 240–402–4363, *Aneesh.Deoras@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the adjunctive predictive cardiovascular indicator as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

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. 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.

We believe this De Novo classification will enhance patients' access to beneficial innovation. 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 less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On September 26, 2016, FDA received Edwards Lifesciences, LLC's request for De Novo classification of the Acumen Hypotension Prediction Index (HPI) Feature Software. 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 March 16, 2018, 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 870.2210.[1] We have named the generic type of device adjunctive predictive cardiovascular indicator, and it is identified as a prescription device that uses software algorithms to analyze cardiovascular vital signs and predict future cardiovascular status or events. This 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 PREDICTIVE CARDIOVASCULAR INDICATOR RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Delayed or incorrect treatment due to erroneous device output resulting from software malfunction or algorithm error.	Software verification, validation, and hazard analysis; Non-clinical performance testing; Clinical performance testing; and Labeling.
Delayed or incorrect treatment due to user misinterpretation or overreliance on indicator	Usability assessment, 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 premarket notification requirements under section 510(k) of the FD&C Act.

At the time of classification, adjunctive predictive cardiovascular indicators are 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 the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' 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 § 870.2210 to subpart C to read as follows:

§ 870.2210 Adjunctive predictive cardiovascular indicator.

(a) *Identification.* The adjunctive predictive cardiovascular indicator is a prescription device that uses software algorithms to analyze cardiovascular

[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.

vital signs and predict future cardiovascular status or events. This 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) 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 impact of all applicable sensor acquisition hardware characteristics and associated hardware specifications;

(iii) A description of sensor data quality control measures;

(iv) A description of all mitigations for user error or failure of any subsystem components (including signal detection, signal analysis, data display, and storage) on output accuracy;

(v) A description of the expected time to patient status or clinical event for all expected outputs, accounting for differences in patient condition and environment; and

(vi) The sensitivity, specificity, positive predictive value, and negative predictive value in both percentage and number form.

(2) A scientific justification for the validity of the predictive cardiovascular indicator algorithm(s) must be provided. This justification must include verification of the algorithm calculations and validation using an independent data set.

(3) A human factors and usability engineering assessment must be provided that evaluates the risk of misinterpretation of device output.

(4) A clinical data assessment must be provided. This assessment must fulfill the following:

(i) The assessment must include a summary of the clinical data used, including source, patient demographics, and any techniques used for annotating and separating the data.

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

(iii) The assessment must demonstrate output consistency using the expected range of data sources and data quality encountered in the intended use population and environment.

(iv) The assessment must evaluate how the device output correlates with the predicted event or status.

(5) Labeling must include:

(i) A description of what the device measures and outputs to the user;

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

(iii) Guidance for interpretation of the measurements, including a statement that the output is adjunctive to other physical vital sign parameters and patient information;

(iv) A specific time or a range of times before the predicted patient status or clinical event occurs, accounting for differences in patient condition and environment;

(v) Key assumptions made during calculation of the output;

(vi) The type(s) of sensor data used, including specification of compatible sensors for data acquisition;

(vii) The expected performance of the device for all intended use populations and environments; and

(viii) Relevant characteristics of the patients studied in the clinical validation (including age, gender, race or ethnicity, and patient condition) and a summary of validation results.

Dated: February 7, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03096 Filed 2–11–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2021–N–0994]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Spore Test Strip

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the spore test strip 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 spore test strip'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 February 14, 2022. The classification was applicable on March 30, 2012.

FOR FURTHER INFORMATION CONTACT: Clarence Murray III, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0270, *Clarence.Murray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the spore test strip as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by placing the device into a lower device class than the automatic class III assignment.

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. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation