(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 parts 801 and 809 regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

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

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

■ 2. Add § 866.1655 to subpart B to read as follows:

§ 866.1655 System for detection of microorganisms and antimicrobial resistance using reporter expression.

(a) *Identification.* A system for detection of microorganisms and antimicrobial resistance using reporter expression is an in vitro diagnostic device intended for the detection and identification of live microorganisms and the detection of associated antimicrobial drug susceptibility or resistance in specimens from patients at risk of colonization or suspected of infection.

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

(1) The intended use for the device in the labeling required under § 809.10 of this chapter must include a detailed description of the targets the device detects, the type of results provided to the user, the clinical indications appropriate for test use, and the specific population(s) for which the device is intended.

(2) Any device used for specimen collection and transport must be FDA-cleared, approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of the specimen types claimed by this device and for the maintenance of viability of the targeted microorganisms; alternatively, the specimen collection device must be cleared in a premarket submission as a part of this device.

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

(i) A detailed description of the device, including reagents, instruments, ancillary materials, applicable specimen collection and transport device(s) and control elements, and a detailed explanation of the methodology, including all pre-analytical methods for handling and processing of specimens and controls to maintain organism viability;

(ii) Detailed descriptions of the test procedure, including the preparation and maintenance of quality controls and the interpretation of test results;

(iii) Detailed discussion of the performance characteristics of the device for all claimed organisms and specimen types based on analytical studies, including evaluation of analytical sensitivity, inclusivity, cross-reactivity, potentially interfering substances and microorganisms, contamination, specimen stability, precision, and reproducibility;

(iv) Detailed discussion of the performance characteristics of the device observed in a clinical study performed on a population that is consistent with the intended use population in comparison to the results obtained by a reference or comparator method determined to be acceptable by FDA, for microbial detection, identification, and antimicrobial susceptibility testing; and

(v) A limiting statement indicating that a negative test result does not preclude colonization or infection with organisms that do not express detectable levels of the reporter that is identified by the device.

(4) Design verification and validation must include:

(i) A detailed description of the device, including an explanation of the technology, hardware, software, and consumables, as well as an explanation of the result algorithms and method(s) of data processing from signal acquisition to result assignment;

(ii) A detailed description of the impact of any software, including software applications and hardware-based devices that incorporate software, on the device's functions;

(iii) Detailed documentation of the analytical and clinical studies required in paragraphs (b)(3)(iii) and (iv) of this section, including the study protocols containing descriptions of the test methods, prescribed methods of data analysis and acceptance criteria, final study reports, and data line listings;

(iv) Detailed documentation of quality control procedures, including an explanation of how quality control materials were selected, the recommended frequency of testing, methods of control preparation, acceptance criteria for performance and the results from quality control testing performed during the analytical and clinical studies required under paragraphs (b)(3)(iii) and (iv) of this section;

(v) Detailed documentation of studies performed to establish onboard and in-use reagent stability, including the test method(s), data analysis plans, acceptance criteria, final study reports, and data line listings;

(vi) Detailed documentation of studies to establish reagent shelf-life for the assay kit and each applicable specimen collection and transport device, including study protocols containing descriptions of the test method(s), data analysis plans, and acceptance criteria; and

(vii) Documentation of an appropriate end user device training program that will be offered as part of efforts to assure appropriate conduct of the assay and to mitigate the risk associated with false results, including failure to use the device correctly or correctly interpret results.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02368 Filed 2–3–22; 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–2021–N–0913]

Medical Devices; Cardiovascular Devices; Classification of the Photoplethysmograph Analysis Software for Over-the-Counter Use

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

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the photoplethysmograph analysis software for over-the-counter use 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 photoplethysmograph analysis software for over-the-counter use'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 4, 2022. The classification was applicable on September 11, 2018.

FOR FURTHER INFORMATION CONTACT: Jennifer Kozen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2272, Silver Spring, MD 20993–0002, 301–796–5813, *Jennifer.Shih@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the photoplethysmograph analysis software for over-the-counter use 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 (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 Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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 August 9, 2018, FDA received Apple Inc.'s request for De Novo classification of the Irregular Rhythm Notification 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 September 11, 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 870.2790.[1] We have named the generic type of device photoplethysmograph analysis software for over-the-counter use, and it is identified as a device that analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

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.

[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.

TABLE 1—PHOTOPLETHYSMOGRAPH ANALYSIS SOFTWARE FOR OVER-THE-COUNTER USE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Poor quality incoming photoplethysmograph (PPG) signal resulting in failure to detect irregular heart rhythms.	Clinical performance testing, Human factors testing, and Labeling.
Misinterpretation and/or over-reliance on device output, leading to: • Failure to seek treatment despite acute symptoms (*e.g.,* fluttering sensation in the chest, lightheadedness, and irregular pulse). • Discontinuing or modifying treatment for chronic heart condition.	Human factors testing, and Labeling.
False negative resulting in failure to detect irregular heart rhythms and delay of further evaluation or treatment.	Clinical performance testing; Software verification, validation, and hazard analysis; Non-clinical performance testing; and Labeling.
False positive resulting in additional unnecessary medical procedures ..	Clinical performance testing; Software verification, validation, and hazard analysis; Non-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 premarket notification requirements under section 510(k) of the FD&C Act.

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 § 870.2790 to subpart C to read as follows:

§ 870.2790 Photoplethysmograph analysis software for over-the-counter use.

(a) *Identification.* A photoplethysmograph analysis software device for over-the-counter use analyzes photoplethysmograph data and provides information for identifying irregular heart rhythms. This device is not intended to provide a diagnosis.

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

(1) Clinical performance testing must demonstrate the performance characteristics of the detection algorithm under anticipated conditions of use.

(2) Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

(3) Non-clinical performance testing must demonstrate the ability of the device to detect adequate photoplethysmograph signal quality.

(4) Human factors and usability testing must demonstrate the following:

(i) The user can correctly use the device based solely on reading the device labeling; and

(ii) The user can correctly interpret the device output and understand when to seek medical care.

(5) Labeling must include:

(i) Hardware platform and operating system requirements;

(ii) Situations in which the device may not operate at an expected performance level;

(iii) A summary of the clinical performance testing conducted with the device;

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

(v) Guidance on interpretation of any results.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02358 Filed 2–3–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2021–N–0948]

Medical Devices; General and Plastic Surgery Devices; Classification of the Carbon Dioxide Gas Controlled Tissue Expander

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 carbon dioxide gas