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

controlled tissue expander 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 carbon dioxide gas controlled tissue expander'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 December 21, 2016.

FOR FURTHER INFORMATION CONTACT: Tajanay Ki, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4553, Silver Spring, MD 20993–0002, 301–796–6441, *Tajanay.Ki@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the carbon dioxide gas controlled tissue expander 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 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 c(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 December 8, 2015, FDA received AirXpanders' request for De Novo classification of the AeroForm® Tissue Expander System. 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 section 513(a)(1)(B) of the FD&C Act). 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 December 21, 2016, 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 878.3510.[1] We have named the generic type of device carbon dioxide gas-controlled tissue expander, and it is identified as a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

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—CARBON DIOXIDE GAS CONTROLLED TISSUE EXPANDER RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Pain	Labeling; and
• From overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Tissue damage	In-vivo performance testing; Labeling; and
• From overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Prolonged treatment time	In-vivo performance testing;
• Due to under expansion because of carbon dioxide permeation	Non-clinical performance testing; Labeling; and
• Due to overexpansion with carbon dioxide	Software verification, validation and hazard analysis.
Re-operation	In-vivo performance testing and Non-clinical performance testing.
• Due to no expansion because of device failure	
• Due to overexpansion with carbon dioxide	
Under expansion, overexpansion, or no expansion	Electromagnetic compatibility, electrical safety, and wireless compatibility testing; Labeling;
• Due to interference with other devices	Software verification, validation and hazard analysis;
• Due to user error	Human factors testing; and Patient training.
Adverse tissue reaction	Biocompatibility evaluation.
Infection	Sterilization validation and Shelf life testing.

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. In order 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, carbon dioxide gas controlled tissue expanders 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. 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 878

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 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for part 878 continues to read as follows:

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

■ 2. Add § 878.3510 to subpart D to read as follows:

§ 878.3510 Carbon dioxide gas controlled tissue expander.

(a) *Identification.* A carbon dioxide gas controlled tissue expander is a prescription device intended for temporary subcutaneous or submuscular implantation to stretch the skin for surgical applications, specifically to develop surgical flaps and additional tissue coverage. The device is made of an inflatable elastomer shell and is filled with carbon dioxide gas. The device utilizes a remote controller to administer doses of carbon dioxide gas from an implanted canister inside the device.

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

(1) In-vivo performance testing must be conducted to obtain the adverse event profile associated with use, and demonstrate that the device performs as intended under anticipated conditions of use.

(2) The patient-contacting components of the device must be demonstrated to be biocompatible.

(3) Performance data must demonstrate the sterility of patient-contacting components of the device.

(4) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Cycle testing of expander showing that there are no leaks or tears after repeated cycling;

(ii) Mechanical assessment of implanted carbon dioxide (CO_2) canister including high impact testing;

(iii) Leak testing of expander showing that device does not leak CO_2;

(iv) Assessment of gas permeability during expansion and after full expansion; and

(v) Mechanical assessment of expander (tensile set, breaking force, shell joint test, and fused or adhered joint testing).

(5) Performance data must be provided to demonstrate the electromagnetic compatibility, electrical safety, and wireless compatibility of the device.

(6) Software verification, validation, and hazard analysis must be performed.

(7) Performance data must support shelf life by demonstrating continued sterility of the device or the sterile components, package integrity, and device functionality over the identified shelf life.

(8) Human factors testing and analysis must validate that the device design and labeling are sufficient for the end user.

(9) Physician labeling must include:

(i) The operating parameters, name, and model number of the indicated external dosage controller;

(ii) Information on how the device operates and the typical course of treatment;

(iii) Information on the population for which the device has been demonstrated to be effective;

(iv) A detailed summary of the device technical parameters; and

(v) Provisions for choosing an appropriate size implant that would be exchanged for the tissue expander.

(10) Patient labeling must include:

(i) Warnings, precautions, and contraindications, and adverse events/complications;

(ii) Information on how the device operates and the typical course of treatment;

(iii) The probable risks and benefits associated with the use of the device;

(iv) Post-operative care instructions; and

(v) Alternative treatments.

(11) Patient training must include instructions for device use, when it may be necessary to contact a physician, and cautionary measures to take when the device is implanted.

Dated: January 26, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–02357 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 880

[Docket No. FDA–2021–N–0998]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Alternate Controller Enabled Infusion Pump

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the alternate controller enabled infusion pump 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 alternate controller enabled infusion pump'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:

Effective date: This order is effective February 4, 2022.

Applicability date: The classification was applicable on February 14, 2019.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357, *Ryan.Lubert@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the alternate controller enabled infusion pump 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 October 29, 2018, FDA received Tandem Diabetes Care, Inc.'s request for De Novo classification of the t:slim X2