airspace at Ardmore, OK. Subsequent to publication, the FAA identified typographic errors that occurred when the notice to proposed rulemaking was transposed to the final rule in the Class E Airspace Areas Designated as an Extension to a Class D or Class E Surface Area and Class E airspace extending upward from 700 feet above the surface airspace legal descriptions. This action corrects those errors.

Class D and Class E airspace designations are published in paragraph 5000, 6002, and 6005, respectively, of FAA Order JO 7400.11F dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class D and Class E airspace designations listed in this document will be subsequently published in FAA Order JO 7400.11.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment Class D and Class E Airspace; Ardmore, OK, published in the **Federal Register** of October 26, 2021 (86 FR 59015), FR Doc. 2021–23008, is corrected as follows:

71.1 [Amended]

■ On page 59016, column 2, line 41, amend to read, ''Airport extending from the 4.3-mile radius of''.

■ On page 59016, column 2, line 60, amend to read, ''That airspace extending upward from''.

Issued in Fort Worth, Texas, on November 29, 2021.

Martin A. Skinner,

Acting Manager, Operations Support Group ATO Central Service Center.

[FR Doc. 2021–26187 Filed 12–1–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2021–N–0622]

Medical Devices; Anesthesiology Devices; Classification of the Isocapnic Ventilation Device

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 isocapnic ventilation device 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 isocapnic ventilation device'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 December 2, 2021. The classification was applicable on March 14, 2019.

FOR FURTHER INFORMATION CONTACT: Todd Courtney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1216, Silver Spring, MD 20993–0002, 301–796–6371, *Todd.Courtney@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the isocapnic ventilation device 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 (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.

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 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), 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 18, 2017, Thornhill Research, Inc. submitted a request for De Novo classification of the ClearMate. 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 14, 2019, 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 868.5480.[1] We have named the generic type of device isocapnic ventilation device, and it is identified as a prescription device used to administer a blend of carbon dioxide and oxygen gases to a patient to induce hyperventilation. This device may be labeled for use with breathing circuits made of reservoir bags (21 CFR 868.5320), oxygen cannulas (21 CFR 868.5340), masks (21 CFR 868.5550), valves (21 CFR 868.5870), resuscitation bags (21 CFR 868.5915), and/or tubing (21 CFR 868.5925).

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—ISOCAPNIC VENTILATION DEVICE RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Hypocapnia (lacking CO_2).	Nonclinical performance testing, and Labeling.
Hypercapnia (excess CO_2).	Nonclinical performance testing, and Labeling.
Hypoxemia (lacking O_2).	Nonclinical performance testing, and Labeling.
High airway pressure (*e.g.,* barotrauma).	Nonclinical performance testing, and Labeling.
Adverse tissue reaction.	Biocompatibility evaluation.

[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.

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).

At the time of classification, isocapnic ventilation devices 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 868

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 868 is amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

■ 1. The authority citation for part 868 continues to read as follows:

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

■ 2. Add § 868.5480 to subpart F to read as follows:

§ 868.5480 Isocapnic ventilation device.

(a) *Identification.* An isocapnic ventilation device is a prescription device used to administer a blend of carbon dioxide and oxygen gases to a patient to induce hyperventilation. This device may be labeled for use with breathing circuits made of reservoir bags (§ 868.5320), oxygen cannulas (§ 868.5340), masks (§ 868.5550), valves (§ 868.5870), resuscitation bags (§ 868.5915), and/or tubing (§ 868.5925).

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

(1) Nonclinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use, including the following performance characteristics:

(i) Gas concentration accuracy testing for the range of intended concentrations;

(ii) Airway pressure delivery accuracy testing;

(iii) Supplemental O_2 flowrate accuracy testing;

(iv) Alarm testing; and

(v) Use life testing.

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

(3) Labeling must include the following:

(i) Instructions for use;

(ii) A precaution that monitoring of capnography is necessary during treatment with non-spontaneously breathing patients; and

(iii) Use life specification.

Dated: November 29, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26201 Filed 12–1–21; 8:45 am]

BILLING CODE 4164–01–P