publish notice of a rulemaking in the **Federal Register** and provide an opportunity for public comment. This requirement does not apply, however, if the agency ''for good cause finds . . . that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.'' [11] The APA also generally requires that an agency publish an adopted rule in the **Federal Register** at least 30 days before it becomes effective. This requirement does not apply, however, if the agency finds good cause for making the rule effective sooner.[12]

Given the temporary nature of the relief contemplated by the interim final temporary rules and the significant and immediate impact of Hurricane Michael and its aftermath on issuers in affected areas, as discussed above, the Commission finds that good cause exists to dispense with notice and comment as impracticable and unnecessary, and to act immediately to amend Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A.[13] Further, the interim final temporary rules will not affect the burden or cost estimates associated with existing collections of information under Regulation Crowdfunding and Regulation A for purposes of the Paperwork Reduction Act of 1995.[14]

V. Statutory Basis and Text of Amendments

We are adopting amendments to Rule 202 of Regulation Crowdfunding and Rule 257 of Regulation A under the authority set forth in the Securities Act (15 U.S.C. 77a *et seq.*), particularly, Section 28 thereof.

List of Subjects

17 CFR Part 227

Crowdfunding, Funding portals, Intermediaries, Reporting and recordkeeping requirements, Securities.

17 CFR Part 230

Reporting and recordkeeping requirements, Securities.

[11] 5 U.S.C. 553(b)(3)(B).

[12] 5 U.S.C. 553(d)(3).

[13] This finding also satisfies the requirements of 5 U.S.C. 808(2), allowing the interim final temporary rules to become effective notwithstanding the requirement of 5 U.S.C. 801 (if a federal agency finds that notice and public comment are impractical, unnecessary or contrary to the public interest, a rule shall take effect at such time as the federal agency promulgating the rule determines). The interim final temporary rules also do not require analysis under the Regulatory Flexibility Act. *See* 5 U.S.C. 604(a) (requiring a final regulatory flexibility analysis only for rules required by the APA or other law to undergo notice and comment).

[14] 44 U.S.C. 3501 *et seq.*

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

■ 1. The authority citation for part 227 is revised to read as follows:

Authority: 15 U.S.C. 77d, 77d–1, 77s, 77z–3, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

■ 2. Amend § 227.202 by adding paragraph (d) to read as follows:

§ 227.202 Ongoing reporting requirements.

* * * * *

(d) *Temporary relief from certain reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by this section, 17 CFR 227.203(a)(3)), or 17 CFR 227.203(b) during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (d)(1) of this section, the issuer must disclose that it is relying on this paragraph (d) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

■ 3. The authority citation for part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77b note, 77c, 77d, 77f, 77g, 77h, 77j, 77r, 77s, 77z–3, 77sss, 78c, 78d, 78j, 78l, 78m, 78n, 78o, 78o–7 note, 78t, 78w, 78ll(d), 78mm, 80a–8, 80a–24, 80a–28, 80a–29, 80a–30, and 80a–37, and Pub. L. 112–106, sec. 201(a), sec. 401, 126 Stat. 313 (2012), unless otherwise noted.

* * * * *

■ 4. Amend § 230.257 by adding paragraph (g) to read as follows:

§ 230.257 Periodic and current reporting; exit report.

(g) *Temporary relief from ongoing reporting requirements.* (1) An issuer that is not able to meet a filing deadline for any report or form required to be filed by 17 CFR 230.252(f)(2)(i) or this section during the period from and including October 10, 2018 to and including November 21, 2018 due to Hurricane Michael and its aftermath shall be deemed to have satisfied the filing deadline for such report or form if the issuer files such report or form with the Commission on or before November 23, 2018.

(2) In any report or form filed pursuant to paragraph (g)(1) of this section, the issuer must disclose that it is relying on this paragraph (g) and state the reasons why, in good faith, it could not file such report or form on a timely basis.

By the Commission.

Dated: October 16, 2018.

Brent J. Fields,

Secretary.

[FR Doc. 2018–22930 Filed 10–17–18; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. FDA–2018–N–3684]

Medical Devices; Anesthesiology Devices; Classification of the Positive Airway Pressure Delivery System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the positive airway pressure delivery system 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 positive airway pressure delivery system'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, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on June 5, 2018.

FOR FURTHER INFORMATION CONTACT: Deepika Arora Lakhani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2543, Silver Spring, MD 20993–0002, 301–796–4042, *Deepika.Lakhani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the positive airway pressure delivery system 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 reducing regulatory burdens 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and 21 CFR part 807 (21 U.S.C. 360(k) and part 807, respectively).

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 (21 U.S.C. 360c(f)(2)). 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 shall 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 (21 U.S.C. 360c(a)(1)). Although the device was automatically 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, in part by reducing regulatory burdens. 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 PMA 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 December 14, 2017, FRESCA Medical submitted a request for De Novo classification of the CURVE™ Positive Airway Pressure 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 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 June 5, 2018, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 868.5273. We have named the generic type of device positive airway pressure delivery system, and it is identified as a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

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—POSITIVE AIRWAY PRESSURE DELIVERY SYSTEM RISKS AND MITIGATION MEASURES

Identified risks	Mitigation measures
Adverse tissue reaction	Biocompatibility evaluation, and Labeling.
Electromagnetic interference with other devices	Electromagnetic compatibility testing, and Labeling.
Infection	Reprocessing validation, and Labeling.
Device software failure leading to ineffective treatment	Software verification, validation, and hazard analysis.
Device hardware failure/malfunction leading to high airway pressure, carbon dioxide rebreathing or ineffective treatment.	Non-clinical performance testing, and Labeling.
Electrical shock injury or thermal injury	Electrical safety, thermal safety, and mechanical testing; Software verification, validation, and hazard analysis; and Labeling.
Use error leading to ineffective therapy or patient injury	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. 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, positive airway pressure delivery systems 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 and 21 CFR 801.5, as long as the conditions of 21 CFR 801.109 are met (referring to 21 U.S.C. 352(f)(1)).

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. 3501–3520). 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 collection of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in part 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, 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 § 868.5273 to subpart F to read as follows:

§ 868.5273 Positive airway pressure delivery system.

(a) *Identification.* A positive airway pressure delivery system is a prescription noninvasive ventilatory device that delivers expiratory positive airway pressure for patients suffering from obstructive sleep apnea. The system also provides positive airway pressure during incipient apnea. The system may include a dedicated flow generator and a patient interface.

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

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

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:

(i) Waveform testing must simulate breathing conditions and evaluate pressure and airflow response over a range and combination of high and low breath rates and tidal volumes.

(ii) Use life testing must demonstrate adequate device performance over the labeled use life of the device.

(iii) Device integrity testing must demonstrate that the device can withstand typical forces expected during use.

(iv) Carbon dioxide rebreathing testing must be performed.

(v) System flow rate, maximum expiratory pressure, inhalation pressure, and intra-mask static pressure testing must be performed.

(vi) Air bolus testing must demonstrate that the device can withstand worst-case scenario air pressures.

(vii) Maximum limited pressure testing of the flow generator in single fault condition must be performed.

(viii) Maximum output temperature testing of delivered gas, if humidified, must be performed.

(3) Performance data must validate reprocessing instructions for any reusable components of the device.

(4) Performance data must demonstrate the electrical, thermal, and mechanical safety and the electromagnetic compatibility of the device.

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

(6) Labeling must include the following:

(i) Therapy pressure range;

(ii) Use life and replacement schedule for all components;

(iii) Cleaning instructions; and

(iv) Instructions for assembly and connection of device components.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22840 Filed 10–18–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–3696]

Medical Devices; General and Plastic Surgery Devices; Classification of the Wound Autofluorescence Imaging Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the wound autofluorescence imaging device into class I. We are taking this action because we have determined that classifying the device into class I 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, in part by reducing regulatory burdens.

DATES: This order is effective October 19, 2018. The classification was applicable on July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Yasaman Ardeshirpour, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G455, Silver Spring, MD, 20993–0002, 240–402–3706, *Yasaman.Ardeshirpour@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: