



June 5, 2018

FRESCA Medical
Mary Mooney
Vice President of RA/CA/QA
1291 Puerta Del Sol, Suite 200
San Clemente, California 92673

Re: DEN170089

Trade/Device Name: CURVE™ Positive Airway Pressure System

Regulation Number: 21 CFR 868.5273

Regulation Name: Positive airway pressure delivery system

Regulatory Class: Class II

Product Code: QBY

Dated: December 13, 2017

Received: December 14, 2017

Dear Mary Mooney:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the CURVE Positive Airway Pressure System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

The CURVE™ Positive Airway Pressure System is intended to treat Obstructive Sleep Apnea by delivering a therapeutic breathing pressure to a patient. It provides positive airway pressure during expiration and also during an incipient apnea. The system includes a dedicated flow generator and a patient interface, and is intended for use in the home environment. This system is to be used by adult patients weighing more than 66 lbs (30 kg).

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the CURVE Positive Airway Pressure System, and substantially equivalent devices of this generic type, into Class II under the generic name positive airway pressure delivery system.

FDA identifies this generic type of device as:

Positive airway pressure delivery system. 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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE)

determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On December 14, 2017, FDA received your De Novo requesting classification of the CURVE Positive Airway Pressure System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the CURVE Positive Airway Pressure System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the CURVE Positive Airway Pressure System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	Mitigation Method
Adverse tissue reaction	Biocompatibility evaluation Labeling
Electromagnetic interference with other devices	Electromagnetic compatibility testing Labeling
Infection	Reprocessing validation 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 Labeling
Electrical shock injury or thermal injury	Electrical safety, thermal safety, and mechanical testing Software verification, validation, and hazard analysis Labeling
Use error leading to ineffective therapy or patient injury	Labeling

In combination with the general controls of the FD&C Act, the positive airway pressure delivery system is subject to the following special controls:

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:
 - a. 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.
 - b. Use life testing must demonstrate adequate device performance over the labeled use life of the device.
 - c. Device integrity testing must demonstrate that the device can withstand typical forces expected during use.
 - d. Carbon dioxide rebreathing testing must be performed.
 - e. System flow rate, maximum expiratory pressure, inhalation pressure, and intra-mask static pressure testing must be performed.
 - f. Air bolus testing must demonstrate that the device can withstand worst-case scenario air pressures.
 - g. Maximum limited pressure testing of the flow generator in single fault condition must be performed.
 - h. 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:
 - a. Therapy pressure range;
 - b. Use life and replacement schedule for all components;
 - c. Cleaning instructions; and
 - d. Instructions for assembly and connection of device components.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the positive airway pressure delivery system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact Deepika Arora Lakhani at 301-796-4042.

Sincerely,

Angela C. Krueger
Deputy Director, Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health