August 12, 2024

SoClean, Inc.
℅ John Smith
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20004

Re: DEN210037
Trade/Device Name: SoClean 3+ Bacterial Reduction Device
Regulation Number: 21 CFR 880.6993
Regulation Name: Respiratory accessory microbial reduction device
Regulatory Class: Class II
Product Code: QXQ
Dated: September 15, 2021
Received: September 15, 2021

Dear John Smith:

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 SoClean 3+ Bacterial Reduction Device, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> The SoClean 3+ device is intended to be used as an adjunct to reduce bacterial populations on certain compatible home use CPAP mask and ventilation hoses after cleaning. An *in vitro* 3-log (99.9%) bacterial reduction by SoClean 3+ has been demonstrated for the following bacteria: *Staphylococcus aureus* (ATCC 6538), *Klebsiella aerogenes* (ATCC 13048), *Staphylococcus haemolyticus* (ATCC 29970), *Escherichia coli* (ATCC 11229), *Staphylococcus hominis* (ATCC 27844), *Klebsiella pneumoniae* (ATCC 4352), *Pseudomonas aeruginosa* (ATCC 15442), and *Streptococcus pyogenes* (ATCC 14289) after a complete processing cycle. Any correlation between *in vitro* results and clinical outcome has not been established.
>
> The SoClean 3+ bacterial reduction device is an over-the-counter device for single patient home use. This device must not be used to replace the cleaning procedures as recommended by the CPAP mask and hose manufacturers. SoClean 3+ has been tested for use with ResMed Mirage FX (nasal mask), ResMed ClimateLine Air (tubing), and SlimLine (tubing) for ResMed AirSense 10 CPAP device. The safe use of SoClean 3+ with any other respiratory devices or accessories has not been established.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the SoClean 3+ Bacterial Reduction Device, and substantially equivalent devices of this generic type, into Class II under the generic name respiratory accessory microbial reduction device.

FDA identifies this generic type of device as:

> **Respiratory accessory microbial reduction device.** A respiratory accessory microbial reduction device is a home-use device intended to be used as an adjunct for microbial reduction of compatible respiratory accessories, such as hoses and masks, after cleaning. This device is not intended to replace the original accessory manufacturer's cleaning instructions.

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 announcing the classification.

On September 15, 2021, FDA received your De Novo requesting classification of the SoClean 3+ Bacterial Reduction Device. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the SoClean 3+ Bacterial Reduction Device 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 SoClean 3+ Bacterial Reduction Device 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:

Risks to Health	**Mitigation Measures**
Respiratory tract infection due to device failure leading to inadequate microbial reduction	Non-clinical performance testing Software verification, validation, and hazard analysis Shelf life validation In-use life validation Labeling
Damage to respiratory accessories resulting in reduced performance of respiratory accessories	Non-clinical performance testing Labeling
Adverse events, e.g., respiratory mucous membrane, pulmonary, or skin irritation, due to chemical exposure	Non-clinical performance testing Biocompatibility evaluation Human factors/usability evaluation

	Labeling
Respiratory tract infection due to user error leading to inadequate cleaning of accessory device	Human factors/usability evaluation Labeling
Injury from electrical, mechanical, or thermal hazards	Electrical safety testing Electromagnetic compatibility testing Mechanical and thermal safety testing Software verification, validation, and hazard analysis Labeling

In combination with the general controls of the FD&C Act, the respiratory accessory microbial reduction device is subject to the following special controls:

(1) 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) Microbial reduction testing must demonstrate at least 2 log or greater reduction of the indicated, clinically relevant microorganisms inoculated on the intended respiratory device accessories after the labeled processing (exposure) time;
   (ii) Performance testing must demonstrate that the device can produce the minimum effective dose or concentration of the microbicidal agent that is necessary to achieve the intended 2 log or greater microbial reduction;
   (iii) Device intercompatibility testing must demonstrate that the labeled respiratory device accessories (e.g., masks and hoses) and materials function as intended after worst-case processing with the microbial reduction device; and
   (iv) Performance testing must demonstrate that any release of the microbicidal agent into the use environment is within safe limits for human exposure.
(2) The respiratory device accessories intended to be processed with the microbial reduction device must be demonstrated to be biocompatible.
(3) Performance data must support the shelf life of the device by demonstrating continued device functionality over the labeled shelf life.
(4) Performance data must support the in-use life of the device by demonstrating continued device functionality over the labeled in-use life.
(5) Usability/human factors evaluation must demonstrate that intended users can correctly use the device, based solely on reading the instructions for use.
(6) Software verification, validation, and hazard analysis must be performed.
(7) Performance data must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device.
(8) Performance data must demonstrate thermal and mechanical safety of the device.
(9) Labeling must include:
   (i) Directions for use including:
      (A) A statement that the device is not intended to replace the respiratory accessory device manufacturer’s recommended cleaning procedures;
      (B) Instructions for how to determine the minimum effective dose or concentration is achieved to ensure the device is functioning as intended;
      (C) Instructions for how to detect and respond to electrical, mechanical, thermal, or chemical hazardous operating conditions;

(D) Instructions for periodic maintenance and cleaning/reprocessing of the microbial reduction device;

(ii) An expiration date or shelf life;

(iii) Use life information;

(iv) Information on respiratory device accessories or materials that can and cannot be used with the microbial reduction device. This information must also be disclosed in the package label; and

(v) Safety information regarding exposure to hazardous chemicals or compounds, process residues, or degraded materials from the use of the microbial reduction device and related adverse reactions.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

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 respiratory accessory microbial reduction device 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Yongqing Chen at 240-402-9433.

Sincerely,

Barton Sachs -S
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