DE NOVO CLASSIFICATION REQUEST FOR SOCLEAN 3+ BACTERIAL REDUCTION DEVICE

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 880.6993

CLASSIFICATION: Class II

PRODUCT CODE: QXQ

BACKGROUND

DEVICE NAME: SoClean 3+ Bacterial Reduction Device

SUBMISSION NUMBER: DEN210037

DATE DE NOVO RECEIVED: March 23, 2022

SPONSOR INFORMATION:

SoClean, Inc.
1 Vose Farm Road
Peterborough, New Hampshire 03458

INDICATIONS FOR USE

The SoClean 3+ bacterial reduction device is indicated as follows:

> 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.

DEVICE DESCRIPTION

SoClean 3+ is an ozone-generating device used as an adjunct for bacterial reduction of certain compatible continuous positive airway pressure (CPAP) mask and hoses after performing the cleaning steps as recommended per the procedures of the original mask and hose manufacturer.

To use the device, the CPAP Hose is disconnected from the CPAP machine and inserted into the Hose Port on the SoClean 3+. The other end of the CPAP Hose (near where the CPAP Masks attaches) is routed through the SoClean 3+ Hose Slot and the CPAP Mask is placed inside the SoClean 3+ Microbial Reduction Chamber. The lid of the SoClean 3+ is then closed, and a "Microbial Reduction Cycle" is initiated which generates and conveys humidified ozone through the CPAP Hose and CPAP Mask and into the Microbial Reduction Chamber. Prior to its exhaust, ozone generated from SoClean 3+ is converted to molecular oxygen via an Ozone Catalyst Filter located on the SoClean 3+ device. SoClean 3+'s general processing architecture is diagramed in Figure 1 below, and Figure 2 provides a graphical illustration of the device's use configuration. Figure 3 shows how CPAP Masks rest within the SoClean 3+ Microbial Reduction Chamber during the processing cycles.

(b)(4)

Figure 1: SoClean 3+ System Function Diagram

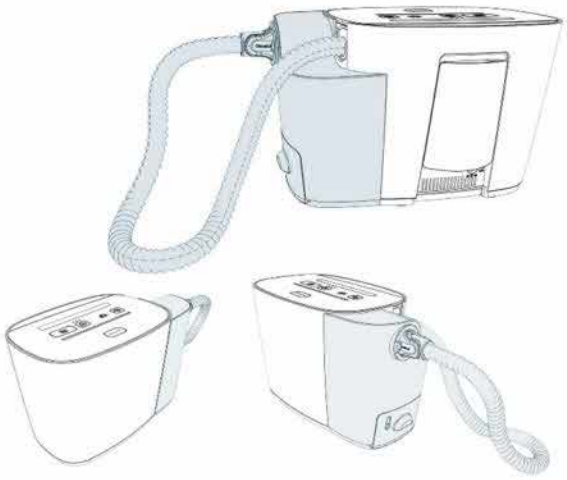

Figure 2: SoClean 3+ In Use Configuration

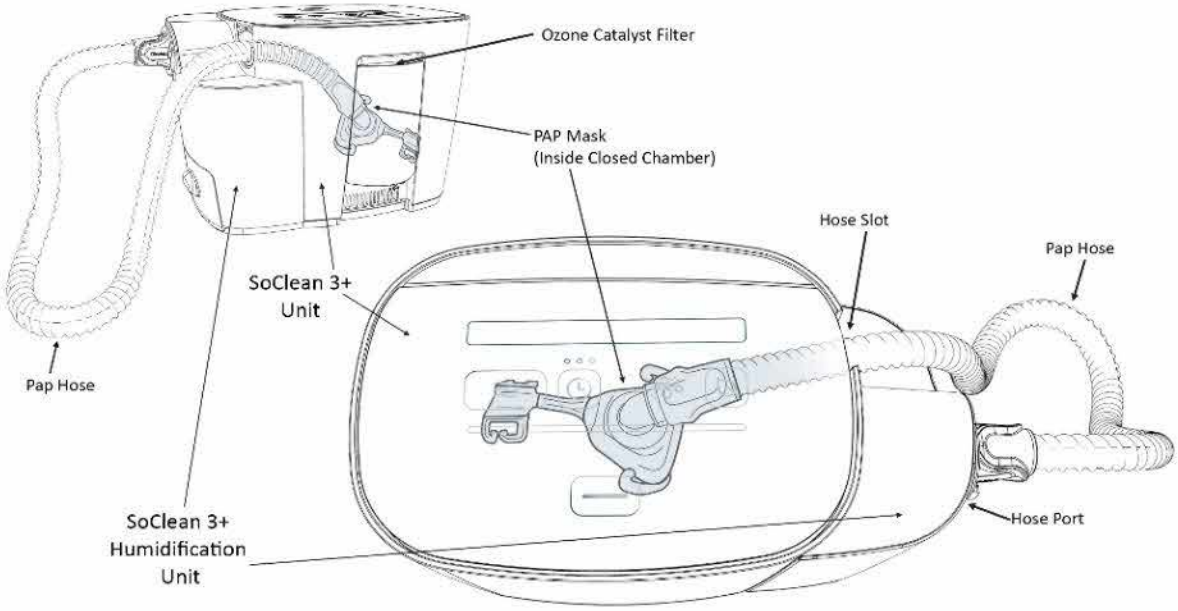

Figure 3: CPAP Mask Location During SoClean 3+ processing cycles

SoClean 3+ treatment is accomplished via a user-initiated and pre-programmed Microbial Reduction Cycle. During this cycle, SoClean 3+ produces ozone which is humidified in the SoClean 3+ Humidification Unit (Figure 4) and conveyed through the CPAP Hose to the CPAP Mask and into the SoClean 3+ Microbial Reduction Chamber. A strong oxidant, ozone reduces bacteria on CPAP Mask and Hose surfaces by reacting with and damaging cell membranes and other biomolecules. This damage can occur either via a direct reaction between ozone and/or through reactions with the radical by-products of ozone decomposition.

Humidification Unit

(b)(4)

Figure 4: SoClean 3+ Humidification Unit

The SoClean 3+ Microbial Reduction Cycle takes approximately 90 minutes to complete and encompasses the following stepwise phases:

- Step 1 – Buildup Phase (builds up ozone levels in the system, 6-minute duration),
- Step 2 – Pulsing Phase (pulses ozone into the system for 10-second periods interspersed with 65-second dwell periods; 72-minute duration),
- Step 3 – Purge Phase (pumps fresh air without ozone through the system to remove residual ozone; 12-minute duration).

To initiate a Microbial Reduction Cycle, the following conditions must be met:

- A CPAP Hose must be inserted and detected by the SoClean 3+ (2 places: connection to the Hose Port and the Hose Slot),
- A valid Ozone Catalyst Filter must be inserted and detected,
- The Filter Door must be closed, and
- The SoClean 3+ Microbial Reduction Chamber lid must be closed.

Once these conditions are satisfied, a Microbial Reduction Cycle can be initiated via the User Interface (UI) by pressing the Microbial Reduction Cycle Button. Alternatively, the UI can allow for a Microbial Reduction Cycle to be started following a 2, 4, or 8-hour delay. When the Microbial Reduction Cycle is successfully completed, the Microbial Reduction level icon will light up green. The Microbial Reduction Level Icon remains illuminated until the lid is opened. If the Microbial Reduction Level Icon is orange, the system has detected either ozone concentrations outside of the specified limits or humidity levels in the bucket below a specified value. The ozone and relative humidity (RH) specifications for SoClean 3+ are 270 ± 15 ppm and ≥ 70%, respectively.

SoClean 3+ can also perform a Fresh Air Cycle, where only the Air Pump and the Exhaust Fan operate for 5 minutes to move fresh air through the CPAP airway. This freshens the air within the CPAP airway before CPAP use. Ozone is not generated during the Fresh Air Cycle. No bactericidal efficacy claims, or other indications are made for the Fresh Air Cycle. Pre-programmed settings allow for the running of only 3 Fresh Air Cycles before a Microbial Reduction Cycle must be run, and LED indicators allow user to distinguish between whether a Microbial Reduction Cycle or a Fresh Air Cycle was last run.

SoClean 3+ includes an Ultraviolet (UV) ozone sensor that monitors ozone concentrations, providing feedback to the Ozone Generator itself for ozone production adjustment and to the SoClean 3+ user via LED lights on the UI when measured ozone concentrations are above or below the prespecified 270 ± 15 ppm range.

Based on in vitro testing, SoClean 3+ demonstrated a 3-log bacterial reduction on the following bacteria: *S. aureus* ATCC 6538, *K. aerogenes* ATCC 13048, *S. haemolyticus* ATCC 29970, *E. coli* ATCC 11229, *S. hominis* ATCC 27844, *K. pneumoniae* ATCC 4352, *P. aeruginosa* ATCC 15442, and *S. pyogenes* ATCC 14289. Correlation between *in vitro* results and any clinical outcome has not been established.

The above *in vitro* 3-log bacterial reduction was established, according to the laboratory condition, on test article (Climateline Air Hose, SlimLine Hose, and Mirage FX Nasal Mask)

that had either been conditioned (have undergone five (5) SoClean 3+ ozone pre-treatment cycles) or conditioned at the End of Useful Life (EOUL) (have undergone no less than 183 SoClean 3+ ozone pre-treatment cycles).

SoClean 3+ is intended for home use by CPAP user or lay person. The intended use environments include an electrical outlet in a well-ventilated room. Once the microbial reduction cycle has been initiated, the users should leave the room for the duration of the cycle, which takes 90 minutes to complete.

SUMMARY OF BENCH STUDIES

BACTERIAL REDUCTION AND SHELF LIFE

The SoClean 3+ bacterial reduction device is **not** intended for cleaning, disinfection, sanitization, or sterilization; it is intended to be used as an adjunct for bacterial reduction of certain compatible home use CPAP masks and ventilation hoses after the original CPAP accessory manufacturer's recommended cleaning procedures are performed. Performance related to bacterial reduction was reviewed as a part of the performance testing. The device includes instructions for bacterial reduction of CPAP accessories. Specifically, the sponsor has included bacterial reduction instructions that SoClean 3+ can be used with one specific ResMed CPAP Mask (Mirage FX) and two specific ResMed CPAP Hoses (ClimateLine Air, SlimLine).

The storage stability study is provided to support:

(i) a six-month shelf life of the product from the date of manufacture of the unopened product; and

(ii) an in-use period of two months of the opened container from the date of opening under the storage/use conditions at 10-32 °C and 15-65 % relative humidity (RH).

COMPATIBILITY

CPAP Mask and Hose compatibility testing was conducted in accordance with the following standard scientific practices with respect to design, documentation, etc.

- IEC 60601-1:2005+A1:2012+A2:2020. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Clause 11.1.1
- ISO 17510:2015. Medical devices -- Sleep apnea breathing therapy -- Masks and application accessories, Annex B, Annex C, Annex F, Annex G
- ISO 80601-2-70:2020
- Medical Electrical Equipment – Part 2-70: Particular requirements for basic safety and essential performance of sleep apnea breathing therapy equipment, Clause 201.11.1.2.2
- ISO 5356-1, Anesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets

The results from compatibility testing, which also included visual and mechanical evaluation, show that using the SoClean 3+ as the bacterial reduction device for

processing ResMed CPAP Mask (Mirage FX) and ResMed CPAP Hoses (ClimateLine Air and SlimLine) for up to 6 months (183 days at 1 bacterial reduction cycle/day) does not adversely affect their safety or functionality. However, the compatible CPAP Mask and Hoses may still undergo limited performance change (due to memory foam, natural rubber and/or nylon degradation), and discoloration (yellowing on silicone portions of mask) by the end of their use life.

BIOCOMPATIBILITY

The SoClean 3+ does not directly contact the patient. However, SoClean 3+ processed PAP accessories contact patients via the skin (PAP Masks) and through gas pathway (PAP Masks and Ventilation Hoses). Therefore, SoClean 3+ is categorized as both a surface device and an externally communicating device with tissue contact and permanent contact duration (>30 days), in accordance with Guidance for Industry and Food and Drug Administration Staff -Use of International Standard ISO10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'.

The sponsor provided the following studies to assess the potential toxicity of SoClean 3+ processed PAP accessories to a user.

- Cytotoxicity, irritation/intracutaneous reactivity, and sensitization on CPAP accessories after conditioning with three back-to-back cycles and conditioning to EOUL. The test article extracts met the requirements of the tests and showed no evidence of cytotoxicity, irritation, or sensitization under the testing condition.
- Volatile Organic Compounds (VOCs) and Particulate Matter (PM) tests on CPAP accessories after conditioning with three (3) back-to-back cycles and conditioning to EOUL. The test article extracts met the requirements of the tests and the acceptance criteria of ISO 18562-2 Test for emission of particulate matter and ISO 18562-3 Test for emission of volatile organic compounds were met.

The sponsor provided exhaustive chemical extractable and leachable testing for Trace Metals, Volatile Organic Compounds (VOC), Semi-Volatile Organic Compounds (SVOC), and Non-Volatile Organic Compounds (NVOC). Toxicological risk assessment for systemic toxicity, genotoxicity, and carcinogenicity of the chemical extractables and leachables showed that the probable risk for patient exposure to SoClean 3+ processed CPAP accessories is low.

The sponsor also provided testing to demonstrate that the amount of ozone released into the environment during processing and remaining on the accessories after processing are below 0.05 ppm as specified in 21 CFR 801.415.

SOFTWARE AND CYBERSECURITY

The SoClean 3+ device contains an air pump, fan, humidifier, ozone generator, catalyst filter, microbial reduction chamber, humidification unit, and a User Interface (UI) made up primarily of physical push buttons and Light-Emitting Diode (LED) indicators lights.

The device has physical buttons and LEDs to implement the user interface, as well as a progress bar, consisting of a sequence of LEDs.

Certain SoClean 3+ functionality is controlled by firmware.

- The internal ozone generator.
- Signals from optical sensors on the device.
- Logging to a memory chip to store device logs for major system events.
- Capable of communicating with Bluetooth Low Energy (hereafter BLE). Note that BLE functionality is specifically designed to be utilized by the manufacturer and is disabled for end-users.
- Capable of communicating via a Command-Line Interface (CLI) over a serial (UART) interface during manufacturing and testing.

The sponsor provided the following assessments, demonstrating that the probable risk is low:

- Level of concern as "Major"
- Device hazard analysis
- Software requirements specification (SRS)
- Architecture design chart
- Software design document (SDS)
- Traceability analysis
- Software Development Environment Description
- Verification and Validation documentation (V&V)
- Revision level history
- Unresolved anomalies
- Cybersecurity

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

The EMC and Electrical Safety was evaluated to mitigate the risk of electrical fault resulting in injury to patient or user. The following Electrical/ Mechanical/Thermal Safety, and electromagnetic compatibility (EMC) testing has been performed:

- Radiated Emissions: CISPR11 ed6.2 (2015 +A1:2016 +A2:2019), FCC 47CFR Part 15 Subpart B (2023-08)
- AC Mains Conducted Emissions: CISPR11 ed6.2 (2015 +A1:2016 +A2:2019)
- Harmonics: IEC 61000-3-2 ed3.2 (2005 +A1:2008 +A2:2009)
- Flicker: IEC 61000-3-3 ed3.0 (2013-05)
- Electro-Static Discharge Immunity Test: IEC 61000-4-2 ed2.0 (2008-12), CENELEC EN 61000-4-2 (2009)
- Radiated, Radio-Frequency, Electromagnetic Immunity: IEC 61000-4-3 ed3.0 (with A1:2007+A2:2010), CENELEC EN 61000-4-3 (2006), A1 (2008) and A2 (2010)
- Immunity to Proximity Fields from FR Wireless Communications Equipment
- Electrical Fast Transient/Burst Immunity Test: IEC 61000-4-4 ed3.0 (2012-04), CENELEC EN 61000-4-4 (2012)

- Immunity to Surges: IEC 61000-4-5 ed3.1 (2014 +A1:2017), CENELEC EN 61000-4-5 (2014)
- Radio-Frequency, Electromagnetic Immunity Test: IEC 61000-4-6 ed4.0 (2013), CENELEC EN 61000-4-6 (2014)
- Power Frequency Magnetic Field Immunity Test: IEC 61000-4-8 ed2.0 (2009-09)
- Voltage Dips/Interruptions Immunity Test: IEC 61000-4-11:2014 +A1:2017, CENELEC EN 61000-4-11 (2004)
- Immunity to Proximity Magnetic Fields in the Frequency Range of 9 kHz to 13.56 MHz IEC 61000-4-39 ed1.0 (2017-03)

All testing and results were adequate and met the above standards requirements.

HUMAN FACTORS

A simulated-use human factors (HF) study was provided in accordance with FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices." It included participants representative of the positive airway pressure (PAP) patient users, and caregivers who may facilitate set-up and daily use of the device on behalf of the PAP patient user. During the session, participants (16 patient users and 15 caregivers) were provided with SoClean 3+ that were targeted in this validation study. Specifically, participants first engaged in simulated first-time use of the SoClean 3+, divided between a setup scenario (first 13 study tasks) and a use scenario (next 7 study tasks), and then by knowledge tasks (last 14 tasks). Following the session, participants answered questions and provided feedback regarding use-related issues and the product itself. The study included 34 assessments which evaluated the critical tasks for using the product and found that users understood.

The provided human factors validation testing results, analyses, and conclusions established that SoClean 3+ is safe and effective for the intended users, its intended uses, and use environments.

PERFORMANCE TESTING – BENCH

The sponsor conducted the following performance conditions and tests to support that the device can achieve its intended use:

- A six-month shelf life (unopened) and two-month in-use life have been demonstrated.
- The test article from compatible ResMed Mirage FX mask and ResMed ClimateLine and SlimLine (ventilation hoses) had either been conditioned (have undergone five (5) SoClean 3+ ozone pre-treatment cycles) or conditioned until End of Useful Life (EOUL, have undergone >= 183 SoClean 3 + ozone pre-treatment cycles). Each test configuration contained three replicates.
- The tested microorganisms included the following eight bacteria: *Staphylococcus aureus* ATCC 6538, *Staphylococcus haemolyticus* ATCC 29970, *Pseudomonas aeruginosa* ATCC 15442, *Staphylococcus hominis* ATCC 27844, *Streptococcus pyogenes* ATCC 14289, *Klebsiella pneumoniae* ATCC 4352, *Klebsiella*

aerogenes ATCC 13048, and *Escherichia coli* ATCC 11229. The target inoculum amount was equal to or above 1 x 10^6 CFU per device. Appropriate extraction control, recovery factor, positive control, negative control, and neutralization control have been included for each test configuration.

- As a worse-case condition, all SoClean 3+ units utilized for testing were characterized to produce ozone at or below the minimum specification of 255 ppm over a shorter Microbial Reduction Cycle time (70 minutes). A 3-log (99.9%) bacterial reduction for all tested bacteria has been demonstrated on the above conditions.
- The firmware has been modified, the Design Verification Evaluation and Testing Support reports are able to demonstrate that the ozone sensor and feedback loop (a) consistently generates ozone within the required concentration specification (270 ± 15 ppm), and (b) accurately informs users when ozone concentrations are outside of this range.

LABELING

The labeling consists of a user guide and package labels. The user guide contains a description of the device (including the mechanism of action of bacterial reduction; in vitro bacterial log-reduction test results), contraindications, warnings, precautions, instructions for processing three compatible CPAP accessories [SoClean 3+ has been tested for use with ResMed Mirage FX (mask), ResMed ClimateLine Air (tubing), and SlimLine (tubing) for ResMed AirSense 10], and information on shelf-life, use-life, maintenance, storage, transport conditions, and disposal. The user guide includes a statement that SoClean 3+ should not be used as a replacement for routine cleaning as recommended by the CPAP accessory manufacturer.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of a respiratory accessory microbial reduction device:

Identified Risks to Health and Mitigation Measures

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Benefit

The bench studies performed support bacterial reduction using the SoClean 3+ device for processing respiratory accessory devices by demonstrating that bacteria on the washed respiratory accessory devices were reduced by at least 3-log on eight (8) different pure-cultured vegetative microorganisms. The subject bacterial reduction device, an ozone-generating device with 72-minute processing time, is intended to be used by patient user and/or caregiver in a home environment. The probable benefit of SoClean 3+ is to serve as an adjunct for bacterial reduction of certain compatible CPAP respiratory accessories, on the condition that the manufacturer's recommended cleaning procedures were performed before the use of SoClean 3+ device. Limitations of the testing include that the bacterial reduction of SoClean 3+ device must be in addition to CPAP accessory manufacturer's cleaning procedures. The clinical benefit of added bacterial reduction from the device use after CPAP accessory manufacturer's cleaning procedures is unknown. No clinical testing was performed and as such, the *in vitro* results should not be correlated with any clinical outcome.

Risk

The identified risks include but are not limited to inadequate microbial reduction causing patient respiratory tract infection, CPAP accessory incompatible with microbial reduction device reducing CPAP therapy benefits, adverse events caused by exposure to microbicidal agent, residues, condensate, and/or degraded materials, and inappropriate labeling causing use/user errors. These risks can be mitigated with appropriate performance testing, material compatibility testing, biocompatibility testing and toxicological risk assessment, as well as human factors studies and by the special controls and labeling.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the available information above, the following indications for use statement is supported:

> 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.

The probable benefits outweigh the probable risks for the SoClean 3+ bacterial reduction device. The device provides benefits, and the risks can be mitigated using general controls and the identified special controls.

CONCLUSION

The De Novo request for the SoClean 3+ Bacterial Reduction Device is granted and the device is classified as follows:

> Product Code: QXQ
> Device Type: Respiratory accessory microbial reduction device
> Regulation Number: 21 CFR 880.6993
> Class: II