October 10, 2025

SoClean, Inc.
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Square
555 13th Street, NW
Washington, District of Columbia 20004

Re: K243815
Trade/Device Name: SoClean 3+
Regulation Number: 21 CFR 880.6993
Regulation Name: Respiratory Accessory Microbial Reduction Device
Regulatory Class: Class II
Product Code: QXQ
Dated: September 9, 2025
Received: September 9, 2025

Dear John J. Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, 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).

Sincerely,

KATHARINE SEGARS -S

Katharine Segars, Ph.D.
Assistant Director
DHT4C: Division of Infection Control Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243815

Device Name

SoClean 3+

Indications for Use *(Describe)*

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 (A TCC 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 AirFit P10 (mask), ResMed ClimateLine Air (tubing), and Slimline (tubing) for ResMed AirSense 10 CP AP device. The safe use of SoClean 3+ with any other respiratory devices or accessories has not been established.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(K) SUMMARY

SoClean's SoClean 3+

Submitter:

SoClean, Inc.
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201-400-0314
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510(K) Number: K243815

Date Prepared: October 9, 2025

Name of Device: SoClean 3+

Common or Usual Name: Respiratory accessory microbial reduction device

Classification: 21 CFR 880.6993

Regulatory Class: Class II

Product Code: QXQ

Predicate Device: SoClean 3+ (DEN210037)

Device Description:

SoClean 3+ is an ozone-generating device intended to reduce populations of bacteria on the surfaces of Continuous Positive Airway Pressure (CPAP) Masks and Hoses. SoClean 3+ treats CPAP Masks and Hoses while remaining disconnected from the CPAP machine. SoClean 3+ treatment is accomplished via a user-initiated and pre-programmed Bacterial Reduction Cycle. During this cycle, SoClean 3+ produces ozone which is humidified in the SoClean 3+ Humidification Unit and conveyed through the CPAP Hose to the CPAP Mask and into the SoClean 3+ Bacterial Reduction Chamber. A strong oxidant, ozone reduces bacteria on CPAP Mask and Hose surfaces by reacting with and damaging cell membranes and other biomolecules..

Intended Use / 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 (A TCC 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 AirFit P10 (mask), ResMed ClimateLine Air (tubing), and Slimline (tubing) for ResMed AirSense 10 CP AP device. The safe use of SoClean 3+ with any other respiratory devices or accessories has not been established.

Summary of Technological Characteristics:

The technological characteristics and the principles of operation of the SoClean 3+ device remain the same as and unchanged from those cleared under DEN210037 with the exception of the minor design updates discussed in further detail below.

As a general summary of unchanged aspects of the device design, SoClean 3+ treats CPAP Masks and Hoses while remaining disconnected from the CPAP machine. SoClean 3+ treatment is accomplished via a user-initiated and pre-programmed Bacterial Reduction Cycle. During this cycle, SoClean 3+ produces ozone which is humidified in the SoClean 3+ Humidification Unit and conveyed through the CPAP Hose to the CPAP Mask and into the SoClean 3+ Bacterial Reduction Chamber. A strong oxidant, ozone reduces bacteria on CPAP Mask and Hose surfaces by reacting with and damaging cell membranes and other biomolecules.. The SoClean 3+ Bacterial 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).

As compared to the SoClean 3+ cleared under DEN210037, the following minor updates have been implemented:

Simplified Humidifier Drawer:

The original SoClean 3+ design (DEN210037) utilizes a horizontally opening humidifier drawer with a 4-bar linkage to accommodate the humidifier tank and raises it upon closing such that the water wick can interface vertically with the bottom of the piezoelectric atomizer. In the updated SoClean 3+ design, users access the humidifier tank for routine refilling/maintenance by pressing a button located on the exterior of the humidifier drawer. This button releases the humidifier drawer such that it moves upward vertically as an intact unit on a rail system, at which point the humidifier tank can be removed for routine refilling/maintenance. When these activities are completed, the user simply returns the humidifier tank to its original position.

Modularized Humidifier Components for Manufacturing:
The humidifier components of the SoClean 3+ have been modularized in order to improve the manufacturing process and improve product use life. The humidifier tank lid has been simplified by incorporating the wick cage into the lid instead of utilizing separate parts. To accommodate this approach, an updated snap feature was incorporated to retain the wick holder to the cage to ensure adequate engagement.

Additionally, updates to the device's useful life validation plan and associated labeling have been made.

A table comparing the key features of the subject and predicate devices is provided below.

	Predicate Device **DEN210037**	**Subject Device** **K243815**	**Difference** **Discussion**
Intended Use / 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 (A TCC 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.	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 (A TCC 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.	Similar The expansion of compatible PAP devices does not alter the intended use or clinical utility of the product, and validation of compatibility relies upon the same scientific methods as the prior DEN210037 clearance. Thus, no new questions of safety and/or effectiveness arise.

	SoClean 3+ has been tested for use with ResMed Mirage FX (nasal mask), ResMed ClimateLine Air (tubing), and Slimline (tubing) for ResMed AirSense 10 CP AP device. The safe use of SoClean 3+ with any other respiratory devices or accessories has not been established.	SoClean 3+ has been tested for use with ResMed Mirage FX (nasal mask), ResMed AirFit P10 (mask), ResMed ClimateLine Air (tubing), and Slimline (tubing) for ResMed AirSense 10 CP AP device. The safe use of SoClean 3+ with any other respiratory devices or accessories has not been established.	
User Population	Over-the-counter device for single patient home use.	Over-the-counter device for single patient home use.	Identical
Compatible CPAP Masks and Hoses	ResMed Mirage FX (nasal mask), ResMed ClimateLine Air (tubing), and Slimline (tubing) for ResMed AirSense 10 CPAP device	ResMed Mirage FX (nasal mask), ResMed ClimateLine Air (tubing), Slimline (tubing), and AirFit P10 for ResMed AirSense 10 CPAP device	Similar All CPAP Masks and Hoses listed have been validated as compatible.
Bacterial Reduction Cycle Profile	Profile: - 6 minute buildup phase - 72 minutes pulsing phase - 12 minute purge phase Ozone Generator: 270 ppm	Profile: - 6 minute buildup phase - 72 minutes pulsing phase - 12 minute purge phase Ozone Generator: 270 ppm	Identical
Generated Ozone Specification	270 ± 15 ppm	270 ± 15 ppm	Identical
UV Ozone Sensor	Included	Included	Identical
Humidification Unit	Included	Included	Similar As described above, minor updates to the humidifier unit have been implemented to facilitate large-scale production. These changes do not impact the safety nor performance of the device and have been empirically validated as such.
Relative Humidity (RH) Sensor	Included	Included	Identical
Relative Humidity (RH) Specifications	≥70% RH	≥70% RH	Identical

Power Source	Mains Power Only	Mains Power Only	Identical
Safety Checks	To initiate a Bacterial 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.	To initiate a Bacterial 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.	Identical
Shelf Life	6 Months	6 Months	Similar The future shelf life and use life extensions will be based on real-time shelf life followed by real-time use life validation. As the shelf and useful life validation methods remain nearly identical and this update does not impact device functionality, no new questions of safety/effectiveness arise.
Use Life	2 Months	3 Months	
Sterilization	Non-sterile	Non-sterile	Identical

Performance Data:

Much of the prior testing submitted and accepted in DEN210037 remain applicable to support the subject device. Nevertheless, and per the company's formal risk analyses, SoClean has conducted additional Non-Clinical confirmatory testing to ensure that all potential risks have been adequately mitigated and that device performance and safety requirements have been met as follows:

Test Name	Purpose/Objective	Acceptance Criteria	Results
Biocompatibility	CPAP Masks conditioned by a SoClean 3+ were subjected to exhaustive extractions as per ISO 10993-12 and tested using GC-MS	ISO 10993-12	Pass
Relative Humidity (RH)	To verify that the relative humidity inside the Hose and Mask Chamber during a Bacterial Reduction Cycle (BRC) meets specifications	Proprietary Specification Limit	Pass

Ozone Production (conducted as part of Useful Life Testing)	To verify that ozone production is within specified limits	Proprietary Specification Limit	Pass
Ambient Ozone	To verify that the levels of accumulated ambient ozone when operating the SoClean 3+ System does not exceed maximum specifications. 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.	<0.05 ppm 21 CFR 801.415.	Pass
Human Factors Study	To determine whether the minor updates to the labeling with respect to the updated humidifier components alter the device's use-related risk profile.	Design updates do not adversely impact device usability	Pass
Shelf Life	To demonstrate that the SoClean 3+ will function as expected following six (6) months of accelerated shelf life.	Proprietary functional testing <0.05 ppm Ambient and Residual Ozone 21 CFR 801.415.	Pass
Use Life	To demonstrate that the SoClean 3+ will function as expected following three (3) months of accelerated use life.	Proprietary functional testing <0.05 ppm Ambient and Residual Ozone 21 CFR 801.415.	Pass

In all instances, the SoClean 3+ functioned as intended and all results observed were passing.

Conclusions:

The SoClean 3+ is as safe and effective as the DEN210037 SoClean 3+. The subject device has the exact same intended uses, indications for use, and principles of operation, and nearly identical technological characteristics, as its predicate device. The minor differences in technological characteristics do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the SoClean 3+ and its predicate devices raise no new issues of safety or effectiveness. The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.