April 29, 2026

LiViliti Health Products Corporation
% Michael Nilo
President, Principal Consultant
Nilo Medical Consulting Group
3706 Butler St. #313
Pittsburgh, Pennsylvania 15201

Re: K252471
Trade/Device Name: Paptizer 360
Regulation Number: 21 CFR 880.6993
Regulation Name: Respiratory Accessory Microbial Reduction Device
Regulatory Class: Class II
Product Code: QXQ
Dated: August 6, 2025
Received: August 6, 2025

Dear Michael Nilo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.

510(k) Number *(if known)*
K252471

Device Name
Paptizer 360

Indications for Use *(Describe)*

The Paptizer 360 device is intended to be used as an adjunct to reduce bacterial populations on certain compatible home use CPAP mask cushions after cleaning. An in vitro 2-log (99%) bacterial reduction by the Paptizer 360 has been demonstrated for the following bacteria: Staphylococcus epidermidis (ATCC#: 12228), Staphylococcus aureus (ATCC#: 6538), Klebsiella pneumoniae (ATCC#: 13883), and Pseudomonas aeruginosa (ATCC#: 15442/10145), Escherichia coli (ATCC#: 11229), and Streptococcus pyogenes (ATCC#: 14289) after a complete processing cycle. Any correlation between in vitro results and clinical outcome has not been established.

The Paptizer 360 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 manufacturers. The Paptizer 360 device has been tested for use with ResMed AirFit F20 (mask cushion only). The safe use of the Paptizer 360 device with any other respiratory devices or accessories, such as headgear, mask frame, and mask elbow, 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.

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510(k) Summary
[as required by 21 CFR 807.92(c)]

Paptizer 360

K252471

Date Prepared:	April 28, 2026
Applicant:	LiViliti Health Products Corp. 2140 SW Main Blvd Lake City, FL 32025
Contact:	Brian Sharpe CEO LiViliti Health Products Corp. 843.343.4476 Brian@liviliti.com
Correspondent:	Michael Nilo President, Principal Consultant Nilo Medical Consulting Group 717.421.4396 michael.nilo@nilomed.com
Trade Name:	Paptizer 360
Device Classification:	Class 2 per 21 CFR 880.6993
Classification Name:	Respiratory Accessory Microbial Reduction Device
Product Code:	QXQ
Predicate Device:	SoClean 3+ Bacterial Reduction Device DEN210037 SoClean, Inc.

Intended Use / Indications For Use:
The Paptizer 360 device is intended to be used as an adjunct to reduce bacterial populations on certain compatible home use CPAP mask cushions after cleaning. An *in vitro* 2-log (99%) bacterial reduction by the Paptizer 360 has been demonstrated for the following bacteria: *Staphylococcus epidermidis* (ATCC#: 12228), *Staphylococcus aureus* (ATCC#: 6538), *Klebsiella pneumoniae* (ATCC#: 13883), and *Pseudomonas aeruginosa* (ATCC#: 15442/10145), *Escherichia coli* (ATCC#: 11229), *and Streptococcus pyogenes* (ATCC#: 14289) after a complete processing cycle. Any correlation between *in vitro* results and clinical outcome has not been established.

The Paptizer 360 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 manufacturers. The Paptizer 360 device has been tested for use with ResMed AirFit F20 (mask cushion only). The safe use of the Paptizer 360 device with any other respiratory devices or accessories, such as headgear, mask frame, and mask elbow, has not been established.

Device Description:
The Paptizer 360 is intended to provide a supplemental, at-home bacterial reduction process for compatible single-patient use CPAP equipment. The Paptizer 360 uses UV-C LEDs to irradiate the surfaces of compatible CPAP equipment. It is not intended to replace the cleaning recommendations outlined in the respective instructions for use (IFU) for the CPAP equipment, but instead, it is used as an additional bacterial reduction step supplementing the existing cleaning methods. The Paptizer 360 has been shown to be compatible with the ResMed AirFit F20 mask cushions, as shown by bacterial reduction validation and biocompatibility data. The Paptizer 360 has been designed to reduce bacterial populations on areas of CPAP Mask Cushions. After the CPAP mask cushion is cleaned following the manufacturer's IFU, then air dried, it can be placed in the Paptizer 360. The Paptizer 360 can reduce bacteria on one CPAP mask cushion at a time in a 30-minute cycle. To start the device, the button on the top of the lid is pressed to start the bacterial reduction cycle. The irradiation bacterial reduction cycle runs for 30 minutes. The locations of all the UV-C LEDs in the Paptizer 360 were designed to ensure all surfaces of CPAP mask cushions are properly irradiated. The Paptizer 360 end user will not be able to modify the cycle time; a 30-minute cycle is always required.

Comparison of Technology to Predicate Device

Device Name	Paptizer 360	SoClean 3+	Comparison
Regulatory Class	Class II	Class II	Same
CFR Section	21 CFR 880.6993	21 CFR 880.6993	Same
FDA Product Code	QXQ – Respiratory accessory microbial reduction device	QXQ – Respiratory accessory microbial reduction device	Same
Manufacturer	LiViliti Health Products Corp	SoClean, Inc.	Different manufacturers listed for subject and predicate devices
Indications for Use	The Paptizer 360 device is intended to be used as an adjunct to reduce bacterial populations on certain compatible home use CPAP mask cushions after cleaning. An *in vitro* 2-log (99%) bacterial reduction by the Paptizer 360 has been demonstrated for the following bacteria: *Staphylococcus epidermidis* (ATCC#: 12228), *Staphylococcus aureus* (ATCC#: 6538), *Klebsiella pneumoniae* (ATCC#: 13883), and *Pseudomonas aeruginosa*	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*	The intended use for the Subject Device is the same as the Predicate Device. The indications for use differ slightly between the two devices based on CPAP accessory compatibility and the bacteria that were evaluated in the different bacterial reduction validations.

	(ATCC#: 15442/10145), *Escherichia coli* (ATCC#: 11229), and *Streptococcus pyogenes* (ATCC#: 14289) after a complete processing cycle. Any correlation between *in vitro* results and clinical outcome has not been established. The Paptizer 360 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 manufacturers. The Paptizer 360 device has been tested for use with ResMed AirFit F20 (mask cushion only). The safe use of the Paptizer 360 device with any other respiratory devices or accessories, such as headgear, mask frame, and mask elbow, has not been established.	*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.	
Use Population	The Paptizer 360 device is intended for use by adult patients who use CPAP machines and their caregivers.	SoClean 3+ is intended for use by CPAP user or lay person.	Same
Use Environment	Home use. The environmental conditions, including ambient light and sound, are variable based on the user's preference	Home use with an electrical outlet in a well-ventilated room.	Similar
Intended User	Lay person	Lay person	Same
Prescription or OTC	Over-the-Counter	Over-the-Counter	Same
Single Use	No	No	Same
Principles of Operation	Paptizer 360 works by delivering ultraviolet radiation onto the mask cushion surface from UV-C LED lights. The UV-C short wavelength kills bacteria.	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	The Paptizer 360 reduces bacteria on compatible CPAP equipment through UV-C irradiation, whereas the SoClean

	Individual, energetic UV-C photons photochemically interact with the RNA and DNA molecules in a bacterium to render these microbes inactive. The UV-C LEDs peak wavelength range is 260-280nm.	SoClean 3+ Humidification Unit 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.	3+ utilizes ozone. While the technology differs, the intended purpose is identical with performance and safety testing, demonstrating the substantial equivalence of the device.
Microbial Reduction Method	UV-C radiation via LEDs in the range of 260nm to 280nm	Ozone generation	While the technology differs, the intended purpose is identical with performance and safety testing, demonstrating the substantial equivalence of the device.
Microbial Reduction Level	An *in vitro* 2-log (99%) bacterial reduction by the Paptizer 360 has been demonstrated for the following bacteria: *Staphylococcus epidermidis* (ATCC#: 12228), *Staphylococcus aureus* (ATCC#: 6538), *Klebsiella pneumoniae* (ATCC#: 13883), and *Pseudomonas aeruginosa* (ATCC#: 15442/10145), *Escherichia coli* (ATCC#: 11229), *and Streptococcus pyogenes* (ATCC#: 14289) after a complete processing cycle.	Based on *in vitro* testing, SoClean 3+ demonstrated a 3-log bacterial reduction of the following bacteria: *S. aureus* ATCC 6538, *K. aerogenes* ATCC 13048, *S. haemolyticus* ATCC 29970, *E. coli* ATCC 11229, *S. hominis* ATCC 278444, *K. pneumoniae* ATCC 4352, *P. aeruginosa* ATCC 15442, and *S. pyrogenes* ATC 14289	While most microorganisms are identical and the bacterial reduction is similar, some different bacteria were tested to reflect clinical relevance and adequate UV-C resistance for the Paptizer device.

Microbial Reduction Cycle Time	30 minutes	90 Minutes	The Paptizer 360 has a shorter bacterial reduction run time. While this represents a difference, it is based on effective use of the bacterial reduction method and not a disparity in safety and/or performance.

Compatibility	The Paptizer 360 is compatible with ResMed AirFit F20 mask cushions only. The safe use of the Paptizer 360 device 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 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 Paptizer 360 is compatible with different CPAP equipment. All the performance and biocompatibility testing included in this 510(k) has shown the Paptizer 360 is compatible with the ResMed AirFit F20 mask cushions. While this represents a difference, it does not present new questions of safety and efficacy.

Shelf Life / Use Life	The Paptizer 360 has a 3-year shelf life. The use life is labeled as 5 years.	The storage study provided supports: (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	The Paptizer 360 has demonstrated the shelf life and use life through real time and accelerated aging testing.

Non-clinical Performance Testing:

Non-clinical laboratory testing was performed to determine substantial equivalence and demonstrate compliance with the special controls. The following testing/assessments were performed:

Test Name	Purpose/Objective	Acceptance Criteria	Results
Bacterial reduction validation	Validate that the Paptizer 360 can successfully reduce microbial load of *Staphylococcus epidermidis* (ATCC#: 12228), *Staphylococcus aureus* (ATCC#: 6538), *Klebsiella pneumoniae* (ATCC#: 13883), and *Pseudomonas aeruginosa* (ATCC#: 15442/10145), *Escherichia coli* (ATCC#: 11229), and *Streptococcus pyogenes* (ATCC#: 14289).	2- log reduction across all bacteria	Pass
Biocompatibility - Cytotoxicity (ISO 10993-5)	To evaluate the potential of device materials or extracts to cause cytotoxic effects on cultured mammalian cells, thereby assessing whether the material induces cell death, lysis, or inhibition of cell growth under in vitro conditions.	Reactivity grade is not greater than grade 2 or a mild reactivity	Pass
Biocompatibility – Sensitization (ISO 10993-10)	To assess the potential of device materials or their extracts to induce local irritation or delayed hypersensitivity (sensitization) following exposure to skin or mucosal tissues, supporting evaluation of local biological responses to the device.	Magnusson and Kligman grade of less than 1 (discrete or patchy erythema or less)	Pass
Biocompatibility – Irritation (ISO 10993-23)	To determine the potential of device materials or extracts to cause irritation following exposure to skin, mucosal surfaces, or other relevant tissues, using validated in vivo or in vitro irritation models in accordance with current regulatory expectations.	The requirements of the test were met if the difference between the test extract overall mean score and corresponding control overall mean score was 1.0 or less.	Pass
Biocompatibility – Particulate Matter (ISO 18562-2)	To quantify and characterize particulate matter emitted from medical devices that deliver breathing gas pathways, in order to assess potential patient exposure to inhalable particles during clinical use.	Test method acceptance criteria met	Pass
Biocompatibility – Volatile Organic Compounds (ISO 18562-3)	To identify and quantify volatile organic compounds emitted from medical devices in the breathing gas pathway, and to evaluate associated toxicological risks to patients from inhalation exposure.	Test method acceptance criteria met; acceptable toxicological risk assessment	Pass
Biocompatibility – Leachables in Condensate (ISO 18562-4)	To identify and quantify non-volatile leachable substances that may be present in condensate from the breathing gas pathway of medical devices, and to assess potential patient exposure and associated toxicological risks.	Test method acceptance criteria met; acceptable toxicological risk assessment	Pass
Ozone Production	Evaluate emissions of ozone as a by-product of UV-C light emitted during device operation.	< 0.05 ppm by volume of air circulating in device OR < 0.05 ppm in atmosphere of enclosed space	Pass
Inorganic Gas Production	Evaluate potential for air emissions if inorganic gases as potential by-products of operation of Paptizer 360.	Device does not present significant toxicological risks following acute, subacute, subchronic or chronic exposure, as determined by a toxicological risk assessment.	Pass
Compatibility Testing	Evaluate the compatibility of CPAP Mask Cushions subjected to bacterial reduction in the Paptizer 360 UV-C irradiation chamber. The testing will assess whether the CPAP mask cushion materials maintain their integrity, specifications, and functionality after simulating 6 months of use, following worst-case repeated UV exposure in the Paptizer 360.	Visual inspection; microscopic surface analysis; compliance with ISO 17510 Annex B and C	Pass

UV Dose Characterization	Characterize the UV-C irradiation dose over the course of the 30-minute run time of the Paptizer 360 bacterial reduction cycle for new and aged devices to demonstrate the continued performance of the UV-C LEDs of the Paptizer 360 units over its stated 5-year use life.	No clinically significant deterioration in dose.	Pass
UV Containment	Measure external UV-C irradiance during a bacterial reduction cycle at points of access and all sides to verify that there is no UV-C exposure through the lifetime of the device.	UV-C measurement from test points A-E, and at lid junction, are below the stated Exposure Level (EL) of IEC 62471 clause 4.3.1	Pass
Interlock Mechanism	Verify that the interlock mechanism maintains functional performance, safety behavior, and mechanical integrity through the lifetime of the device.	All units complete 4,000 cycles; no critical failures occur; all final functional tests pass; wear does not indicate imminent functional failure.	Pass
Shutoff Latency	Determine potential Actinic UV-C hazard exposure using the latency of the LED's shutoff of the Paptizer 360 due to the lid being opened to determine the actinic UV hazard exposure limit for the skin and eye.	UV-C exposure is < 30 J/m_2; LEDs are not able to be turned on while lid is opened.	Pass
Shelf-Life and Use Life	Demonstrate the shelf life and use life through real time and accelerated aging testing.	Visual and functional performance maintained throughout stated shelf-life and use-life.	Pass
Software Verification and Validation	Verify functionality of the Paptizer 360 software in accordance with requirements for a device with IEC 62304 Safety Class B software.	All test results match expected results.	Pass
Human Factors / Usability	Evaluate whether the Paptizer 360 can be used as intended by patients and lay caregivers in a simulated use home environment.	Intended users can safely and effectively use the device.	Pass
EMC	Verify compliance	As defined by IEC 60601-1-2 and IEC TR 60601-4-2	Pass
EMT Safety	Verify compliance with electrical, mechanical, and thermal safety requirements for devices intended for use in the home environment.	As defined by ANSI/AAMI ES60601-1:2005, IEC 60601-1-11, and IEC 60601-1-6.	Pass
Packaging	To evaluate the ability of the packaging system to protect the device from physical damage, environmental exposure, and contamination throughout the intended shelf life and distribution conditions, ensuring that the device remains safe and functional for its intended use.	As defined in ASTM D4169-22	Pass

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device, DEN210037.