May 27, 2025

PreventaMed Technologies, Inc. dba Surfacide Manufacturing
Jeffry Veenhuis
President and CEO
W226N918 Northmound Drive, Suite 300
Waukesha, Wisconsin 53186

Re: K242604
Trade/Device Name: Helios+ UV-C System
Regulation Number: 21 CFR 880.6510
Regulation Name: Whole Room Microbial Reduction Device
Regulatory Class: Class II
Product Code: QXJ
Dated: April 23, 2025
Received: April 23, 2025

Dear Jeffry Veenhuis:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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)*
K242604

Device Name
Helios+ UV-C System

Indications for Use *(Describe)*

Helios+ is a 253.7nm wavelength, high intensity, germicidal UV-C light system intended to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. Helios+ is intended for use in unoccupied operating rooms, hospital rooms and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices. The system is for over-the-counter (OTC) use.

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 K242604

Contact Details		**21 CFR 807.92(a)(1)**
Applicant Name:	PreventaMed Technologies, Inc., dba Surfacide Manufacturing, Inc.	
Applicant Address:	W226N918 Northmound Drive Suite 300 Waukesha, WI 53186 United States	
Applicant Contact Telephone::	+1 (262) 309-6226	
Applicant Contact:	Mr. Jeffry D. Veenhuis, President & CEO	
Applicant Contact Email:	jveenhuis@surfacidemfg.com	
Date Prepared:	May 27, 2025	
Device Name		**21 CFR 807.92(a)(2)**
Device Trade Name:	Helios+ UV-C System	
Classification Name:	Whole Room Microbial Reduction Device	
Regulation Number:	21 CFR 880.6510	
Product Code:	QXJ	
Regulatory Class:	II	
Legally Marketed Predicate Device		**21 CFR 807.92(a)(3)**
Predicate #	DEN230007	
Predicate Trade Name	LightStrike™+	
Product Code	QXJ	
DEN230007	LightStrike™+	

Device Description Summary **21 CFR 807.92(a)(4)**

Surfacide Helios+ is a 253.7nm wavelength, high intensity, germicidal UV-C light system intended to perform microbial reduction on non-porous, non- critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. Helios+ is intended for use in unoccupied operating rooms, hospital rooms and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices.

Helios+ delivers a defined dose to a defined distance and area sufficient for 2-log microbial reduction of vegetative bacteria and *Clostridioides difficile* spores.

Helios+ is used in operating rooms, hospital rooms, and other clinical settings where non-critical medical devices are present.

Helios+ includes 1-3 UV-C emitters, 1-3 safety sensors, a control tablet, and 2 joiners that link the emitters for transport and serve as warning stands when the device is in use. Simultaneous use of multiple UV-C emitters can reduce shadowed areas by providing multiple direct lines of sight to non- critical medical device surfaces.

Indications for Use **21 CFR 807.92(a)(5)**

Helios+ is a 253.7nm wavelength, high intensity, germicidal UV-C light system intended to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. Helios+ is intended for use in unoccupied operating rooms, hospital rooms and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices. The system is for over-the-counter (OTC) use.

Table of Comparison Technological Comparison to Predicate Device			21 CFR 807.92(a)(6)
Feature / Attribute	**Subject Device**	**Predicate Device**	**Comparison Discussion**
Trade Name (Device):	**Surfacide Helios+™ (K242604)**	**Xenex LightStrike™ + (DEN230007)**	**N/A**
Device Type:	Whole room microbial reduction device	Whole room microbial reduction device	Identical
Product Code:	QXJ	QXJ	Identical
Classification Regulation:	21 CFR 880.6510	21 CFR 880.6510	Identical
Class:	II	II	Identical
Rx/OTC:	OTC	OTC	Identical
Intended Use:	Helios+ is a whole room microbial reduction device intended to be used to reduce microbial load on non-critical medical device surfaces following cleaning and disinfection.	LightStrike+ is a whole room microbial reduction device intended to be used to reduce microbial load on non-critical medical device surfaces following cleaning and disinfection.	Similar
Indications for Use:	Helios+ is a 253.7nm wavelength, high intensity, germicidal UV-C light system intended to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. Helios+ is intended for use in unoccupied operating rooms, hospital rooms and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices. The system is for over-the-counter (OTC) use.	The Xenex LightStrikeTM + is a pulsed, broad-spectrum, high intensity, germicidal UV light system intended to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices. LightStrike+ is intended for use in unoccupied operating rooms, hospital rooms and other clinical settings where non-critical medical devices are present as an adjunct to existing manual cleaning and disinfection practices. The system is for over-the-counter (OTC) use.	Different: See notes below
Non-clinical Performance Testing - Microbial Reduction:	Helios+ achieved a 99% (2-log) microbial reduction of select bacterial organisms and *Clostridioides difficile* (spore).	LightStrike+ achieved a 99% (2-log) microbial reduction of select bacterial organisms and *Clostridioides difficile* (spore).	Identical
Physical State:	Portable, remotely operated microbial reduction device. Multiple configurations of one, two or three emitters.	Portable, microbial reduction device operated by an on-device touchpad/display. Single emitter with a singular configuration.	Different: See notes below
Technical Method:	Microbial reduction on surfaces using a germicidal device.	Microbial reduction on surfaces using a germicidal device.	Identical
Target Area:	Unoccupied rooms	Unoccupied rooms	Identical
User:	Cleaning staff	Cleaning staff	Identical
Environment of Use:	Operating rooms, hospital rooms, and other clinical settings where non-critical medical devices are present.	Operating rooms, hospital rooms, and other clinical settings where non-critical medical devices are present.	Identical

FDA identifies a whole room microbial reduction device as a medical device to be used to reduce microbial load on medical device surfaces following cleaning and disinfection. Both Helios+ and the predicate device are portable. Both Helios+ and the predicate device deliver high intensity, germicidal UV-C light system to perform microbial reduction on non-porous, non-critical medical device surfaces, free from visual soiling, after manual cleaning and disinfection practices.

Differences between the proposed Helios+ device and the predicate include:
Helios+ can be deployed in multiple configurations of one, two or three emitters. The predicate device is a single emitter with a singular configuration.
Helios+ is operated remotely with a control tablet. The tablet communicates to UV-C emitters and safety sensors by Bluetooth LE. The predicate device is operated using a GUI on the robot. The microbial reduction cycle starts once the physical button above the user interface screen is pressed and the robot senses the operator has exited the room.
Helios+ uses continuous 253.7nm wavelength, high intensity, germicidal UV-C light. The predicate uses pulsed, broad-spectrum, high intensity,

germicidal UV light.
Surfacide recommends changing all Helios+ lamps at the same time, every two years to ensure consistent output of energy. The predicate flash lamp has a service life of 140 hours and the robot is subject to routine predictive maintenance at the time of lamp change or every 6 months, whichever comes first.
Helios+ uses up to 3 wireless safety sensors to ensure that the UV-C emitters shut off immediately if someone enters the room or approaches them. Operator intervention is required to prevent bystanders from entering the room/area if there are more than 3 entryways. The predicate device uses a tethered motion detection cone to ensure that the UV-C emitter shuts off immediately if someone enters the room or approaches it. Operator intervention is required to prevent bystanders from entering the room/area from any entry point that is not protected by a tethered motion detection cone.

The differences in technological characteristics between the proposed Helios+ device and the selected predicate device do not raise different questions of safety or effectiveness.

Non-Clinical Tests Summary	**21 CFR 807.92(b)(1-2)**

- Optimized kill curve testing results were provided, determining the dosage required for Helios+ to achieve a 2-log reduction of select bacterial organisms and *C. difficile* spores.
- Bacteriostasis of intended in-use surfaces were provided to verify potential inherent bacteriostatic properties of surfaces.
- Recovery validation testing was provided to verify expected effectiveness of microbial recovery methods used to verify microbial reduction system results in a simulated use environment.
- Dose hierarchy of UV-C resistance identified the most resistant microorganisms.
- Simulated use performance testing demonstrated microbial log reduction of the most resistant microorganism on medical device surfaces commensurate with the intended level of microbial reduction (2-log).
- In-use testing was completed to evaluate device performance under real-world conditions. Patient rooms, bathrooms, and operating rooms were sampled before and after Helios+ use. In all the tests, Helios+ delivered a statistically significant reduction in bacterial load.
- Photobiological safety of lamps and lamp system test were provided, to evaluate the safety of the lamp that emits UV light when the robot is in use, conducted using a new lamp, because the light intensity is at its maximum when the lamp is new and that represents the worst-case scenario, per IEC 62471 "Photobiological Safety of Lamps and Lamp Systems." Photobiological lamps and lamp system met IEC 62471 criteria.
- Performance testing was completed to demonstrate the system will prevent exposure and ensure that device operation can only occur in an unoccupied environment.
- Accelerated UV materials damage test results were provided, to evaluate the impact of regular exposure to Helios+ with metallic and non-metallic materials commonly present in healthcare environments, including materials commonly used as medical device enclosures. Materials damage testing results met ISO 4582, ASTM D256-10, and ASTM A370-22 requirements.
- Ozone tests were provided, to demonstrate that Helios+ users are safe per 21 CFR 801.415 "Maximum acceptable level of ozone". Helios+ does not produce measurable ozone. Levels of toxic chemicals were below 29 CFR 1910.1000 acceptance levels.
- Helios+ electrical safety is in conformance with IEC 61010-1, and the electromagnetic compatibility (EMC) is in accordance with IEC 61326-1.
- Adequate cybersecurity and software functionality were demonstrated according to FDA guidance "Content of Premarket Submissions for Device Software Functions" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

CLINICAL TESTING – Non – Applicable

CONCLUSION	**21 CFR 807.92(b)(3)**

The conclusions drawn from the non-clinical testing demonstrates that the proposed subject device is as safe, as effective, and perform as well as or better than the legally marketed predicate device DEN230007.