October 29, 2026

Lumicare Medtech Co., Ltd.
% Lukas Spoegler
Regulatory Affairs Coordinator
Lumicare Pty, Ltd.
Level 6, 15 Orion Rd.
Lane Cove W., NSW 2066
Australia

Re: K260427
Trade/Device Name: Lumicare (ONE);Lumicare (ONE Lite);Lumicare (ONE+)
Regulation Number: 21 CFR 880.6511
Regulation Name: Ultraviolet Radiation Disinfection Chamber Device
Regulatory Class: Class II
Product Code: SCS
Dated: February 10, 2026
Received: February 10, 2026

Dear Lukas Spoegler:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

Dolly Singh Digitally signed by Dolly Singh

For 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)*
K260427

Device Name
Lumicare (ONE);Lumicare (ONE Lite);Lumicare (ONE+)

Indications for Use *(Describe)*
The UVC Disinfection System for Ultrasound Probe is designed to provide High-Level Disinfection (HLD) of ultrasound probes. High-Level Disinfection is achieved by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe.

The UVC Disinfection System for Ultrasound Probe is intended for high-level disinfection of external and endocavity (transvaginal and transrectal) ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for Lumicare UVC Disinfection System for Ultrasound Probe (K260427)

1 Contact Details

1.1 Applicant

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Preparation Date:	October 29, 2026

1.2 Correspondent

Name:	Lumicare Pty Ltd
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Telephone:	+61 478 461 333
Contact:	Mr. Lukas Spoegler
Email:	l.spoegler@lumicare.one

2 Device Name

Trade Name:	Lumicare (ONE^{+}) Lumicare (ONE) Lumicare (ONE Lite)
Common Name:	UVC Disinfection System for Ultrasound Probe
Classification Name:	Ultraviolet Radiation Disinfection Chamber Device
Classification:	Class II
Regulation Number:	21 CFR 880.6511
Product Code(s):	SCS

3 Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
DEN230067	Chronos	SCS

4 Device Description Summary

The Lumicare UVC Disinfection System for Ultrasound Probe is designed to provide High-Level Disinfection (HLD) of ultrasound probes. High-Level Disinfection is achieved by exposure to a dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe.

The UVC Disinfection System for Ultrasound Probe is intended for high-level disinfection of external and endocavity (transvaginal and transrectal) ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

When starting the disinfection cycle, UVC LEDs generate UVC irradiation over all surfaces of the ultrasound probe within the enclosed disinfection chamber. Independent interior dose sensors monitor the accumulated UVC dose. When the required dose is reached, the cycle is automatically stopped, and the disinfection cycle is recorded.

The device is equipped with a fully automated control and traceability system that allows users to verify the disinfection cycle between each patient.

5 Intended Use/Indications for Use

The UVC Disinfection System for Ultrasound Probe is designed to provide High-Level Disinfection (HLD) of ultrasound probes. High-Level Disinfection is achieved by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe.

The UVC Disinfection System for Ultrasound Probe is intended for high-level disinfection of external and endocavity (transvaginal and transrectal) ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

6 Substantial Equivalence Comparison

Feature	Subject Device (K260427)	Predicate Device (DEN230067)	Comparison
General Information			
Device Class	II	II	Same
FDA Product Code	SCS	SCS	Same
FDA Regulation	21 CFR 880.6511	21 CFR 880.6511	Same
Indications for Use			
Indications for Use	The UVC Disinfection System for Ultrasound Probe is designed to provide High-Level Disinfection (HLD) of ultrasound probes. High-Level Disinfection is achieved by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe. The UVC Disinfection System for Ultrasound Probe is intended for high-level disinfection of external and endocavity	Chrones is indicated for use in a healthcare environment to achieve a high-level disinfection of surfaces of external, transvaginal, and transrectal ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.	Same

Feature	Subject Device (K260427)	Predicate Device (DEN230067)	Comparison
	(transvaginal and transrectal) ultrasound probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.		
Technological Characteristics			
Principle of Operation	High-Level Disinfection is achieved by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe.	High-Level Disinfection is achieved by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe.	Same
Disinfectant process	Physical (chemical free)	Physical (chemical free)	Same
Disinfectant	UVC irradiation	UVC irradiation	Same
Critical parameters for HLD	UV Dose	UV Dose	Same
Disinfectant delivery	UVC emitting LEDs	UVC mercury lamps	Different – Lumicare uses UVC LEDs
Disinfection Cycle Monitoring	Integrated cycle monitoring system with continuous UVC dose monitoring and verification, and cycle time monitoring.	Integrated cycle monitoring system with UVC dose monitoring and end-of-cycle verification.	Similar – Lumicare uses continuous UVC dose verification

The subject and predicate device have the same indications for use. The subject and predicate device are both intended for high-level disinfection (HLD) of ultrasound probes in professional healthcare environments.

The subject and predicate devices have substantially equivalent technological characteristics. Both devices have the same operating principle, achieving high-level disinfection by surface exposure to a controlled dose of Ultraviolet-C (UVC) irradiation delivered to a disinfection chamber containing the ultrasound probe. The use of different UVC technologies (LEDs vs. mercury lamps) does not raise any new questions regarding safety and effectiveness. Both devices incorporate cycle monitoring systems to verify disinfection cycle completion. Differences in cycle monitoring do not raise new questions regarding safety or effectiveness, as supported by the subject device's verification testing.

7 Performance Data

7.1 Non-Clinical Tests Summary

Non-clinical performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in the Table below.

Test Details	Acceptance Criteria	Conclusion
Electrical Safety and Electromagnetic Compatibility (EMC) Testing	The subject device is in compliance with IEC 61010-1 and IEC 61010-2-040 for electrical safety and performance, as well as IEC 61326-1 and IEC 60601-1-2 for electromagnetic compatibility (EMC).	Pass
Resistance Testing (UVC Hierarchy)	UVC resistance testing was performed on clinically relevant microorganisms and those known to be resistant to UV radiation. Each microorganism was exposed to a series of UVC dose levels	Pass

Test Details	Acceptance Criteria	Conclusion
	corresponding to different cycle times. The hierarchy of resistance includes mold spores, bacterial spores, bacteria, mycobacteria and fungi. The most resistant microorganism tested was *Aspergillus brasiliensis*.	
Potency Testing	Potency Testing was performed on a panel of microorganisms including clinically relevant and UV resistant microorganisms. Modified testing was used to demonstrate the effectiveness of the subject device following recognized AOAC and ASTM methods. The testing results demonstrate sporicidal, bactericidal, fungicidal, mycobactericidal and virucidal efficacy. Tested microorganisms include *Bacillus spizizenii* (former *Bacillus subtilis), Clostridium sporogenes, Trichophyton interdigitale* (former *Trichophyton mentagrophytes), Poliovirus Type 1, Adenovirus Type 5, Herpes Simplex Virus (HSV) Type 1, Human coronavirus, Human Papillomavirus Type16 (HPV16), Human Papillomavirus Type 18 (HPV18), Staphylococcus aureus, Pseudomonas aeruginosa, Salmonella enterica,* and *Mycobacterium terrae.*	Pass
Simulated-Use Testing	Simulated-Use testing was performed on a selection of worst-case ultrasound probes to demonstrate the effectiveness of the subject device. Based on the results of the UVC hierarchy and potency testing, *Bacillus spizizenii* (formerly *Bacillus subtilis*) was selected as the challenge organism for Simulated-Use testing, including in the presence of residual soil. The probe models were selected to represent challenging conditions for UVC exposure (worst-case) and test locations were identified to assess disinfection performance at sites presenting increased challenges for UVC irradiation. The results demonstrated a microbial reduction of at least 6 $\log_{10}$ at the evaluated test locations, supporting the effectiveness of the subject device under the defined simulated-use conditions.	Pass
In-Use Testing	In-Use testing under real-world clinical use conditions was performed on a selection of endocavity and external ultrasound probes. The in-use testing results demonstrate that the subject device achieved high-level disinfection (HLD) of clinically used ultrasound probes under the tested conditions.	Pass
UVC Safety Testing	UVC irradiation is emitted solely during the disinfection cycle, when the disinfection chamber is sealed and automatically locked, preventing any access. A UVC Leak test was performed to demonstrate that the chamber door effectively prevents UVC leakage during a disinfection cycle and does not pose any risk to the user.	Pass
Door Interlock Testing	Door interlock performance testing was conducted in accordance with IEC 61010-1 to ensure the door remains securely locked during any UVC irradiation.	Pass
Ventilation Testing	Unlike the predicate device, the Lumicare ventilation system does not provide an airflow pathway into the disinfection chamber, and microbial contamination cannot enter the chamber through the ventilation openings. Accordingly, ventilation contamination testing was determined to be not applicable.	Not Applicable
Probe Temperature Safety Testing	Temperature testing was conducted to confirm that ultrasound probe surface temperatures following high-level disinfection in the subject device remain within acceptable limits, avoiding the risk of thermal damage to the probe or burns to users and patients.	Pass
Disinfection Cycle Verification Testing	Testing was performed to verify that the subject device's cycle monitoring system correctly distinguishes between successful and unsuccessful disinfection cycles. The evaluation included scenarios in which the required UVC dose was achieved and scenarios in	Pass

Test Details	Acceptance Criteria	Conclusion
	which the target dose was not met. The system correctly identified the outcome of each test cycle.	
Compatibility Testing	Material compatibility testing with various ultrasound probe manufacturers has been conducted. Ultrasound probe manufacturers have assessed the compatibility of the subject device with their ultrasound probes, evaluating the impact of the high-level disinfection on both material integrity and probe functionality. Furthermore, commonly used ultrasound probe materials were evaluated for compatibility with repeated UVC exposure, including potential effects on mechanical integrity and functional performance.	Pass
Biocompatibility Testing	The subject device does not come into direct or indirect contact with the patient or users. The surface materials of representative ultrasound probes following exposure to the UVC disinfection cycle have been evaluated to confirm that the process does not adversely affect the probes' biocompatibility. Biocompatibility evaluation and testing have been conducted in accordance with the FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".	Pass
Software and Cybersecurity Testing	Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions". Cybersecurity evaluation and testing was conducted as per FDA guidance document "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions".	Pass

7.2 Clinical Tests Summary

Not Applicable

8 Conclusions

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device Chronos from Germitec (DEN230067, Class II (21 CFR 880.6511), product code SCS).