January 29, 2026

UV Smart Technologies B.V.
Thijs Kea
Director
Patrijsweg 74
Rijswijk, ZH 2289EX
Netherlands

Re: K251354
Trade/Device Name: UV Smart D60
Regulation Number: 21 CFR 880.6511
Regulation Name: Ultraviolet Radiation Disinfection Chamber Device
Regulatory Class: Class II
Product Code: SCS
Dated: December 29, 2025
Received: December 29, 2025

Dear Thijs Kea:

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, PhD.
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)*
K251354

Device Name
UV Smart D60

Indications for Use *(Describe)*
The UV Smart D60 is indicated for use in a healthcare environment to achieve a high level disinfection (HLD) of external surfaces of Transesophageal Echocardiogram (TEE) 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.

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510(K) SUMMARY K251354

1. ADMINISTRATIVE INFORMATION

510(k) Owner	UV Smart Technologies B.V.
Address	Patrijsweg 74, Rijswijk, Zuid-Holland, The Netherlands
Phone Number	+31 85 060 9800
Fax Number	N/A
Company Representative	Thijs Kea – Director
Additional Company Representatives	Daan Hoek – Director
Email	info@uv-smart.com
Summary Preparation Date	29 January 2026

2. SUBJECT DEVICE INFORMATION

Type of 510(k) Submission	Traditional
UV Smart Trade Name	UV Smart D60
Subject Device K-Number	K251354
Common Name	UV Smart D60
Classification Name	Ultraviolet Radiation Disinfection Chamber Device
Product Code	SCS
Regulation Number	21 CFR 880.6511
Regulatory Class	Class II
Review Panel	General Hospital

3. PREDICATE DEVICE INFORMATION

Predicate Device Name	Germitec Chronos
Predicate Device Clearance Number	DEN230067
Common Name	Chronos
Classification Name	Ultraviolet Radiation Disinfection Chamber Device
Product Code	SCS
Regulation Number	21 CFR 880.6511
Regulatory Class	Class II
Review Panel	General Hospital

4. DEVICE DESCRIPTION

The UV Smart D60 is indicated for use in a healthcare environment to achieve a high level disinfection (HLD) of external surfaces of Transesophageal Echocardiogram (TEE) probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths (hereafter collectively referred to as the Intended Load).

The UV Smart D60 provides *chemical-free* high level disinfection using Ultraviolet-C (UV-C) light within a fully enclosed disinfection chamber. The system features eight UV-C lamps, UV-C-reflective chamber walls, and UV-C-transmitting instrument holders designed to suspend the intended load in an optimal position. The fixed disinfection cycle time of 120 seconds is the only critical determinant of disinfection efficacy. The disinfection efficacy is verified during each cycle by two independent threshold sensors—one for UV-C dose and one for power consumption.

The UV Smart D60 is intended to be used in healthcare facilities by trained personnel. Prior to disinfection, each soiled instrument must be cleaned at the bedside and manually cleaned in accordance with the original equipment manufacturer (OEM) instructions for use. Under normal operating conditions, the UV Smart D60 has an expected service life of ten years, with preventive maintenance and lamp replacement required annually, as specified in the UV Smart D60's Instructions for Use.

To ensure that the intended load is both physically compatible with the disinfection chamber and capable of receiving the required HLD UV-C dose (Minimum Effective Dose or MED) on its surfaces, the intended load is approved for use with the UV Smart D60. Once approved, the intended load is released for use in the UV Smart D60's traceability system. The UV Smart D60 will not initiate a disinfection cycle unless a registered instrument is recognized, ensuring that only approved instruments can be processed.

Each disinfection cycle accommodates a single instrument, which is suspended entirely within the D60's disinfection chamber—ensuring that all surfaces, including handles and attached cables, receive the MED for validated high level disinfection.

5. INDICATIONS FOR USE

The UV Smart D60 is indicated for use in a healthcare environment to achieve a high level disinfection (HLD) of external surfaces of Transesophageal Echocardiogram (TEE) probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

For ease of reference and comparison between the subject device and predicate device, an overview is provided in Table 1 - Technological Characteristics Comparison.

Table 1 - Technological Characteristics Comparison

Characteristic	UV Smart D60	Predicate Device	Comparison
Regulation Number	880.6511	880.6511	Same
Regulatory Class	Class II	Class II	Same
Product Code	SCS	SCS	Same
Regulation Name	Ultraviolet radiation chamber disinfection device	Ultraviolet radiation chamber disinfection device	Same
Device Property	Disinfection Device	Disinfection Device	Same
Intended Use / Indications for Use	The UV Smart D60 is indicated for use in a healthcare environment to achieve a high level disinfection (HLD) of external surfaces of Transesophageal Echocardiogram (TEE) probes that do not contain lumens and that do not contain indentations or channels that are deeper than their widths.	Chronos 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.	Different The UV Smart D60 is intended for TEE probes.
Input	TEE probes that have been pre-cleaned according to OEM instructions and hospital protocol.	External, transvaginal, and transrectal ultrasound probes that have been pre-cleaned according to OEM instructions and hospital protocol.	Different The UV Smart D60 is intended for TEE probes.
Output	High level disinfected instruments, ready for use on patients.	High level disinfected instruments, ready for use on patients.	Same
Output Measurements	UV-C Dose Verification via photodiode and Power Consumption monitoring via current sensor.	UV-C Dose Verification via multiple photodiodes.	Similar
Independent Monitoring System	Dual-sensor: photodiode for UV-C dose and current sensor for power consumption verification.	Photodiode-based UV-C dose monitoring (multiple sensors).	Different The UV Smart D60 utilizes a variety of sensors for independent monitoring.

Characteristic	UV Smart D60	Predicate Device	Comparison
Report Structure	Detailed report on touchscreen interface including pass/fail status, dose, power, time, date, and traceability.	Pass/fail message on device interface; full report available via optional connected interface.	Different The UV Smart D60 provides detailed traceability on the interface.
Intended Users	Physicians or other licensed practitioners in healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services.	Physicians or other licensed practitioners in healthcare institutions, such as clinics, hospitals, healthcare facilities, residential care facilities and long-term care services.	Same
Ventilation	No ventilation required. Temperature monitoring and control.	Integrated ventilation.	Different The UV Smart D60 does not require ventilation.
Intended Use Environment	Healthcare institutions (Clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)	Healthcare institutions (Clinics, hospitals, healthcare facilities, residential care facilities and long-term care services)	Same
Software device that operates on off-the-shelf hardware	No	No	Same

Both the subject device (UV Smart D60) and the predicate device share similar indications for use, with the primary difference being the intended load for disinfection. The subject device is indicated for high level disinfection of TEE probes, whereas the predicate device is intended for the disinfection of external, transvaginal, and transrectal ultrasound probes.

Another difference lies in the disinfection cycle operation: the predicate device adjusts its cycle duration based on the load, while the subject device uses a fixed disinfection cycle time of 120 seconds. Additionally, the subject device accommodates the entire instrument—including both the insertion portion and the connecting cables—within the disinfection chamber.

. All differences have been thoroughly assessed and supported through appropriate verification and validation testing.

7. NONCLINICAL TESTING

For ease of reference and comparison between performance testing and data of the subject device and predicate device, an overview is provided in Table 2 - Performance Testing Overview.

Table 2 - Performance Testing Overview

Test	Acceptance Criteria	Result
Biocompatibility	An evaluation of the surface materials of representative TEE probes following exposure to the UV-C disinfection cycle was provided. Biocompatibility risk evaluation and testing has been conducted in accordance with the FDA 2020 Biocompatibility Guidance document, Use of International Standard ISO 10993-1, *"Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,"*	Pass
Software & Cybersecurity	Software testing was conducted as per FDA guidance document, "Content a/premarket submissions for Device Software Functions." Cybersecurity testing was conducted as per FDA guidance documents, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" &* *"Post-market Management of Cybersecurity in Medical Devices."*	Pass
Electromagnetic Compatibility & Electrical Safety	Electromagnetic Compatibility (EMC) of the UV Smart D60 device has been evaluated in accordance with IEC 61326-1, *Electrical equipment for measurement, control and laboratory use -EMC requirements -Part I: General requirements, and IEC 60601-1-2, Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance -Collateral Standard: Electromagnetic disturbances Requirements and tests.* Electrical safety testing of the UV Smart D60 device was completed in accordance with IEC 61010-1, *Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1:*	Pass

Test	Acceptance Criteria	Result
	General requirements and *IEC 61010-2-040, Safety requirements for electrical equipment for measurement, control and laboratory use. Part 2-040: Particular requirement for sterilizers and washer-disinfectors used to treat medical materials.*	
UV-C Hierarchy Testing	Performance testing has been conducted to support a side-by-side evaluation of microorganism UV-C resistance. Each microorganism was tested at a series of varying UV-C doses in the UV Smart D60 device. The panel of microorganisms included in UV-C resistance hierarchy testing included bacterial spores, bacteria, mycobacteria, yeast/molds (spores) and *Trichomaceae* family (spore forming molds). A hierarchy of UV-C resistance was determined for the UV Smart D60 device. Based on the results obtained, the most resistant microorganism tested was *Aspergillus brasiliensis*, of the *Trichomaceae* family (spore forming molds).	Pass
Potency Testing	The UV Smart D60 device was tested for potency using the standard array of microbicidal testing to support device efficacy. Modified testing was developed to demonstrate microbicidal potency for the device as there exists no current standard method in place for UV-C disinfection processes. Potency testing was conducted to demonstrate sporicidal, bactericidal, fungicidal, mycobactericidal and virucidal efficacy of the device. Specifically: *Mycobacterium terrae* *Tricophyton mentagrophytes* *Salmonella choleraesuis* *Staphylococcus aureus* *Pseudomonas aeruginosa* *Adenovirus Type 5* *Murine Norovirus* *Poliovirus Type 1* *Herpes Simplex Type 2* *Simian Virus 40*	Pass

Test	Acceptance Criteria	Result
Simulated Use Testing	Simulated use testing was conducted with worst-case TEE probes to demonstrate that the UV Smart D60 can reliably and consistently achieve a > 6 log reduction of the most resistant clinically relevant microorganism (*Bacillus subtilis*) following exposure to the disinfection cycle. Based on the completed hierarchy of resistance testing and the results of potency testing, *Bacillus subtilis* was identified as the most resistant bacterial spore. Based on resistance and clinical relevance, it was chosen for use in Simulated Use testing. Worst-case representatives of a TEE probe (mucous membrane contacting) were selected based on their geometric complexity and difficulty to consistently achieve UV-C HLD. Worst-case locations were identified based on difficulty for UV-C exposure to penetrate and therefore posed the greatest challenge to microbial inactivation. For each of these worst-case locations, a > 6 log microbial reduction was demonstrated for the worst-case instruments.	Pass
Optical Verification on Worst-Case probes	Worst-case TEE probe associated "cold spot" locations on each instrument, underwent optical verification studies to demonstrate that each location received the minimum effective dose (MED) UV-C exposure. All optical measurements at these geometrically worst-case locations were shown to receive the MED following exposure to the UV Smart D60 device's 120 second disinfection cycle.	Pass
In-Use Testing	TEE probes used in a clinical setting were subjected to the UV Smart D60's high level disinfection cycle. The probes were cleaned using cleaning solutions routinely used by the hospitals prior to exposure in the UV Smart D60 system. In-Use testing demonstrated the achievement of HLD on these clinical used TEE probes.	Pass
UV-C Leak test	Leakage testing verified that the chamber door prevents UV-C escape.	Pass

Test	Acceptance Criteria	Result
Door Interlock Test	Door interlock performance testing was conducted in accordance with IEC 61010-1 requirements.	Pass
Verification of ventilation contamination risk control	The UV Smart D60 does not include any form of active ventilation or airflow exchange within its disinfection chamber. Internal temperature is continuously monitored throughout the disinfection cycle, and a built-in safeguard disables the device if elevated temperatures are detected. Disinfection cannot resume until the internal temperature returns to the safe operating range. As a result, no additional risk of microbial contamination is introduced by ventilation, and no filtration or exhaust validation is required.	Pass
Equipment Surface Temperature	Performance testing was conducted to demonstrate the ability of the UV Smart D60 device to control temperatures within the chamber to ensure the inserted instruments do not pose burn risk to the operator or patient. Testing was conducted in accordance with the requirements of IEC 60601-2-37 ultrasound probes) and IEC 60601-2-18 (endoscopic equipment).	Pass
Independent Cycle Monitoring System Performance Testing	Performance testing was conducted to demonstrate the ability of the UV Smart D60 device's independent cycle monitoring system to accurately determine if a completed disinfection cycle is accurately identified as a success or failure. Testing was conducted to simulate conditions both where the target dose was reached and conditions where the target dose was not actually reached. In all test runs the independent monitoring system was able to identify successful and unsuccessful cycles.	Pass
Instrument 3D Scanning Validation	Validation testing was completed to demonstrate that the optical scanning process used is able to accurately capture the geometric complexity of TEE probes. Testing included a range of instrument geometries to challenge the system. Documents provided demonstrate that the method used to acquire 3D scanned files was sufficiently robust to support the optical simulation verification process.	Pass

Test	Acceptance Criteria	Result
Optical Simulation Verification	Optical Simulation verification was conducted to evaluate the interaction between the geometric variations of the TEE probes, and the UV-C dose distribution when exposed to the UV Smart D60 disinfection chamber. Validation of the simulation included worst-case TEE probes identified for each dose group. This validation testing confirmed that the MED was systematically received at the three worst-case-location of the instrument when exposed to the UV-C disinfection cycle.	Pass

8. CLINICAL TESTING

Not applicable for the proposed device.

9. CONCLUSION

The conclusions drawn from the nonclinical and clinical tests demonstrates that the UV Smart D60 is as safe, as effective and performs as well as or better than the legally marketed predicate device Germitec Chronos (DEN230067).