DE NOVO CLASSIFICATION REQUEST FOR GERMITEC CHRONOS

REGULATORY INFORMATION

FDA identifies this generic type of device as:

> **Ultraviolet radiation disinfection chamber device.** An ultraviolet radiation disinfection chamber device is intended to disinfect patient contacting medical devices using UV radiation after the device has been cleaned. Disinfection of the medical device is achieved within an enclosed chamber through the exposure to UV radiation.

NEW REGULATION NUMBER: 21 CFR 880.6511

CLASSIFICATION: Class II

PRODUCT CODE: SCS

BACKGROUND

DEVICE NAME: Germitec Chronos®

SUBMISSION NUMBER: DEN230067

DATE DE NOVO RECEIVED: October 3, 2023

SPONSOR INFORMATION:

Germitec
19 Rue Vauban
33000 Bordeaux, France

INDICATIONS FOR USE

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.

LIMITATIONS

The Germitec Chronos® is intended to be marketed for Over-The-Counter (OTC) use.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS

DEVICE DESCRIPTION

The Germitec Chronos® device is intended to provide Ultraviolet C (UV-C) chemical-free high-level disinfection (HLD) of ultrasound probes within an enclosed disinfection chamber. As defined in FDA Guidance - *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, found at https://www.fda.gov/media/80265/download, HLD is a lethal process utilizing a sterilant under less than sterilizing conditions. The process kills all forms of microbial life except for large numbers of bacterial spores. The subject device is intended for use in health care facilities by trained personnel. The Chronos® is an automated medical device consisting of a sealed disinfection chamber, incorporating multiple UV-C lamps and reflective walls. UV-C dose is identified as the only critical determinant of the effectiveness of the disinfection cycle.

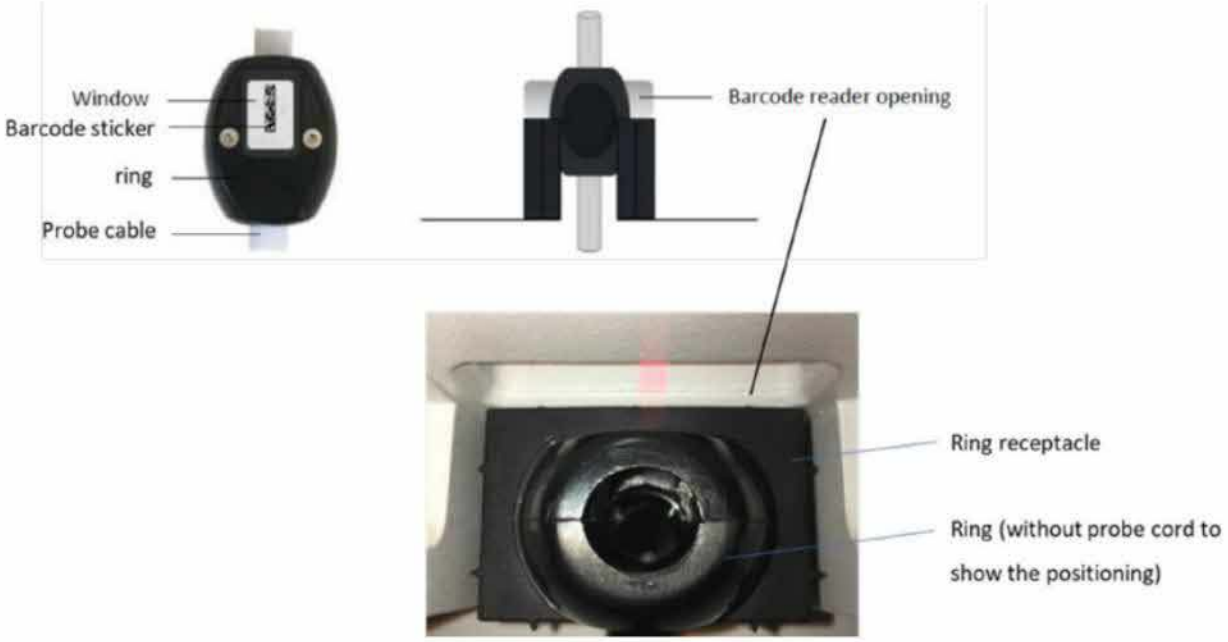
The software is used to determine achievement of the disinfection total dose and acceptance of the automated HLD cycle. The total dose delivered to the surface of each ultrasound probe undergoing the disinfection process is continuously monitored by two optical sensors, UV-C sensitive photodiodes. The control system continuously takes readings from the sensors, tracks progress of the ongoing disinfection cycle, and terminates the disinfection cycle when the cycle-controlling photodiodes indicate that the pre-defined UV-C dose has been achieved. Additionally, the device utilizes an independent cycle monitoring step through the use of a third UV-C photodiode. This independent probe is used to verify that the pre-defined UV-C HLD dose has been delivered.

Pictures of Chronos® - Door Closed (left) and Door Open (right):

Onto each ultrasound probe for which compatibility has been validated, a ring is placed onto the ultrasound cable. This ring is used to set the probe into the proper position within the chamber, as well as to include an identifier barcode. This barcode is read by the Chronos® software, and

provides identification of both the appropriate disinfection dose as well as traceability for the ultrasound probe undergoing disinfection. The encoding of the barcode to each specific probe model and installation of the ring on each probe can only be performed by an authorized service representative from Germitec.

Barcode ring location:



SUMMARY OF BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The Germitec Chronos® is provided non-sterile and does not require additional reprocessing or sterilization. The device requires regular maintenance in order to continue to function as intended.

Annual preventive maintenance activities are defined for general system checks, device cleaning (internal and external components), calibration of optical sensors (UV-C photodiodes) and replacement of the ventilation filter. Additionally, the UV-C lamps must be replaced on a two-year interval, or every 100 hours of cumulative use, whichever comes first. The software provides an indication to the operator of UV-C lamp usable life remaining.

BIOCOMPATIBILITY

The Germitec Chronos® device is designed to provide liquid-free, high-level disinfection of reusable ultrasound probes using UV-C as the germicidal agent. Since UV-C does not remain on the ultrasound probe following completion of an HLD cycle, there is no indirect contact with the patient or personnel conducting HLD reprocessing. The sponsor has

provided an evaluation of the surface materials of representative ultrasound probes following exposure to the UV-C disinfection cycle. 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,"* found at https://www.fda.gov/media/142959/download

SOFTWARE & CYBERSECURITY

The Germitec Chronos® device incorporates a software-based control system used to control and monitor the delivery of UV-C dose required for high level disinfection of reusable ultrasound probes. The control system includes an ultrasound probe identifying system that captures key information about the probe, using a barcode reader, to link it to each disinfection. In addition to controlling the HLD cycle, the Chronos® device software controls system operation, ensures that the device is operating as expected, and communicates potential cycle errors to the user, as well as providing warnings about system status, condition, and reminders regarding preventive maintenance. The software testing was conducted as per FDA guidance document, "*Content of premarket submissions for Device Software Functions,"* found at *https://www.fda.gov/media/153781/download*.

Cybersecurity testing was conducted as per FDA guidance documents, "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"* found at https://www.fda.gov/media/119933/download, and "*Postmarket Management of Cybersecurity in Medical Devices,"* at https://www.fda.gov/media/95862/download.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

Electromagnetic Compatibility (EMC) of the Chronos® device has been evaluated in accordance with IEC 61326-1, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: 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 Chronos® device was completed in accordance with IEC 61010-1, *Safety requirement for electrical equipment for measurement, control and laboratory use. Part 1: 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*. Testing has been successfully completed per the referenced standards, including electrical, mechanical resistance to shock/impact, and mechanical safety testing.

PERFORMANCE TESTING – BENCH

The sponsor conducted the following performance tests to support that the device can achieve its intended use:

- **UV-C Hierarchy of Resistance**

  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 Chronos® device. For the purposes of hierarchy testing, a panel of microorganisms was selected which represented a combination of organisms currently used as surrogates for other HLD processes or organisms reported to be particularly resistant to UV-C in literature. 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 Chronos® device. Based on the results obtained, the most resistant microorganism tested was *Aspergillus brasiliensis*, of the *Trichomaceae* family (spore forming molds).

- **Potency Testing**

  The Chronos® 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. Microbicidal potency testing included the following microorganisms.

Microbicidal Activity	**Organisms Challenged**
Sporicidal	*Bacillus subtilis*
	Bacillus pumilus
	Clostridium sporogenes
Bactericidal	*Deinococcus radiodurans*
	Salmonella enterica
	Staphylococcus aureus
	Pseudomonas aeruginosa
	Paraburkholderia fungorum
Mycobactericidal	*Mycobacterium terrae*
	Mycobacterium bovis
	Mycobacterium avium
Fungicidal	*Candida auris*
	Candida albicans
	Trichophyton mentagrophyte (spore form)
Virucidal	*Poliovirus Type 1*
	Adenovirus Type 5
	Murine Norovirus
	Vaginal Herpes
	Polyomavirus
	HPV16 / HPV18

Sporicidal Activity	Organisms Challenged
Trichomaceae family (spore forming molds)	*Aspergillus brasiliensis*
	Penicillium polonicum (spore form)

Based on the testing documentation provided, the results support the determination of microbicidal potency for the device.

- **Simulated Use Testing**

Simulated use testing was conducted over a range of worst-case ultrasound probes to demonstrate that the Chronos® can reliably and consistently achieve a > 6 log reduction of the surrogate 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 and determined to be the most appropriate for use in Simulated Use testing. Representative transvaginal and transrectal (mucous membrane contacting), and external (skin contacting) ultrasound probes were selected based on their geometric complexity and difficulty to consistently achieve UV HLD.

For each probe, the three 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 ultrasound probes over a range of challenging geometries.

- **Optical Verification on Worst-Case Probes**

Worst-case ultrasound probes and associated "cold spot" locations on each probe, underwent optical verification studies to demonstrate that each location received the minimum effective dose (MED) of (b)(4) mJ/cm^2 UV-C exposure. All optical measurements at these geometrically worst-case locations were shown to receive the MED following exposure to the Chronos® device automated disinfection cycles.

- **In-Use Testing**

Ultrasound probes used in a clinical setting were subjected to the Chronos® automated high level disinfection cycles. Transvaginal and transrectal probes were used with single use probe protective sheath and gel. Transvaginal and transrectal probes were cleaned using cleaning solutions routinely used by hospital. External probes were used without a sheath and only underwent a dry wipe prior to exposure in the Chronos® system. In-Use testing demonstrated the achievement of HLD on these clinical used ultrasound probes.

- **UV-C Leak Test**

  The sponsor has conducted performance testing to support to demonstrate that the chamber door prevents UV-C leakage from the disinfection chamber during a routine disinfection cycle. Documentation was provided to show that the amount of UV-C leakage remained ≤ (b)(nW/cm^2.

- **Door Interlock Test**

  Door interlock performance testing was conducted in accordance with IEC 61010-1 requirements.

- **Verification of ventilation contamination risk control**

  Performance of the Chronos® device ventilation was conducted to support control of excessive heat build up while mitigating potential for probe contamination from outside air. Testing provided documented evidence verifying the ability of the ventilation system to limit microbial contamination entering through the ventilation system.

- **Probe Surface Temperature**

  Performance testing was conducted to demonstrate the ability of the Chronos® device to control temperatures within the chamber to ensure ultrasound probes do not pose burn risk to the operator or patient. Testing was conducted in accordance with IEC 60601-2-37.

- **Independent Cycle Monitoring System Performance Testing**

  Performance testing was conducted to demonstrate the ability of the Chronos® device's independent cycle monitoring system to accurately to 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.

- **Probe 3D Scanning Validation**

  Validation testing was completed to demonstrate that the optical scanning process used is able to accurately capture the geometric complexity of ultrasound probes. Testing included a range of ultrasound probe geometries to challenge the system. Document provided demonstrated that the method used to acquire probe 3D scanned files was sufficiently robust to support the optical simulation verification process.

- **Optical Simulation Verification**

  Optical Simulation verification was conducted to evaluate the interaction between the geometric variations of the ultrasound probes and the UV-C dose distribution when exposed to the Chronos® disinfection chamber. Validation of the simulation included the three worst-case probes identified for each dose group. This validation testing confirmed that the MED was systematically received at the three worst-case-location of the probe when exposed to the automated pre-defined UV-C disinfection cycle.

LABELING

The labeling consists of a product label and User Manual.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of an ultraviolet radiation disinfection chamber device and the measures necessary to mitigate these risks.

Risks to Health	Mitigation Measures
Patient cross-contamination due to device failure or operator error leading to inadequate microbial reduction	Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Exposure to UV radiation, leading to skin and eye damage	Non-clinical performance testing Biocompatibility evaluation Software verification, validation, and hazard analysis Labeling
Incompatibility of the materials intended to be disinfected leading to reduced performance or premature failure	Non-clinical performance testing Biocompatibility analysis Software verification, validation, and hazard analysis Labeling
Electrical shock or thermal hazards	Non-clinical performance testing Electrical safety testing Thermal safety testing
Interference with other devices	Electromagnetic compatibility testing Electrical safety testing

SPECIAL CONTROLS

In combination with the general controls of the FD&C Act, the ultraviolet radiation disinfection chamber device is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Resistance testing must demonstrate the hierarchy of resistance to UV radiation using a panel of microorganisms that are clinically relevant and those known to be resistant to UV radiation;
(ii) Potency testing against bacterial spores, vegetative bacteria, mycobacteria, yeast/molds (spores), spore forming molds and virus, must demonstrate that the UV disinfection device is able to achieve microbial log reduction of a panel of clinically relevant and UV resistant microorganisms, as appropriate for the intended level of disinfection;
(iii) Simulated use testing must evaluate device performance under worst-case use and device conditions, including selection of appropriate challenge microorganism(s), microbial inoculum with residual soil, device complexity, exposure dose, and time, as appropriate for the intended level of disinfection;
(iv) In-use testing must evaluate device performance under real-world clinical use conditions;
(v) Performance testing must demonstrate the photobiological safety of any lamps or lamp systems;
(vi) Performance testing must validate safety features intended to prevent exposure; and
(vii) Performance testing must characterize the long-term material compatibility of UV radiation on clinically relevant surfaces and/or devices following repeated UV disinfection cycle exposure.

(2) Biocompatibility evaluation must demonstrate safe residual levels of chemicals on medical device surfaces and/or gaseous byproducts in air.

(3) Software verification, validation, and hazard analysis must be performed for any software components.

(4) Performance data must demonstrate the electromagnetic compatibility (EMC), thermal and electrical safety of the device.

(5) The labeling must include:

(i) Warnings and instructions to ensure the device is used for UV disinfection purposes, and is not to be used as a sterilant or as part of a sterilization process for medical devices;
(ii) User setup, operating and maintenance procedures;
(iii) Description of the required preparation of equipment for disinfection in the UV chamber device;
(iv) UV hazard warning labels;
(v) Explanation of device safety features; and
(vi) Information regarding material compatibility.

BENEFIT-RISK DETERMINATION

Benefit:

The sponsor demonstrated that the probable benefits include the following:

- Chemical-free, automated, High Level Disinfection (HLD) device for the surfaces of external, transvaginal, and transrectal probes. HLD reprocessing is performed following routine cleaning activities of the reprocessed ultrasound.
- Reduced disinfection duration.
- Traceability of the disinfection process.

Risks:

The risks of the device are based on nonclinical laboratory testing described above.

The main probable risk for the subject device is that a failure in the automated reprocessing cycle does not achieve the required microbial reduction, and high level disinfection is not achieved. Probes which have not been adequately disinfected may lead to patient-to-patient cross-contamination, and an increased health risk associated with infections. Further, additional risks associated with UV exposure, electrical shock and interference with other devices, as well as thermal burns associated with probes following the disinfection cycle have also been identified. Additionally, cybersecurity risks have been identified for the device. These risks have all been mitigated through completion of performance testing, warnings, precautions, and special controls. Human factors testing was deemed not required based on an evaluation of potential high-risk use scenarios and the anticipated level of user interface needed to support routine operation of the device. In addition, In-Use testing was provided to demonstrate real world use conditions.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion

In conclusion, given the testing provided and available information summarized above, for the following indication statement:

> *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.*

The probable benefits outweigh the risks for the Germitec Chronos®. The device provides benefits, and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the Germitec Chronos® is granted and the device is classified as follows:

Product Code: SCS
Device Type: Ultraviolet radiation disinfection chamber device
Regulation Number: 21 CFR 880.6511
Class: II