September 20, 2024

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% Suji Shetty
Executive Vice President
Maxis
3031 Tisch Way Suite 1010
San Jose, California 95128

Re: DEN230067
Trade/Device Name: Chronos®
Regulation Number: 21 CFR 880.6511
Regulation Name: Ultraviolet radiation disinfection chamber device
Regulatory Class: Class II
Product Code: SCS
Dated: September 26, 2023
Received: September 28, 2023

Dear Suji Shetty:

This letter corrects our previous classification order, dated August 28, 2024, to correct the product code.

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Chronos®, an over-the-counter device under 21 CFR Part 801 Subpart C with the following 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.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Chronos®, and substantially equivalent devices of this generic type, into Class II under the generic name ultraviolet radiation disinfection chamber device.

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.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On September 28, 2023, FDA received your De Novo requesting classification of the Chronos®. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Chronos® into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Chronos® can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

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

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.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket

notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ultraviolet radiation disinfection chamber device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Stephen Anisko at Stephen.anisko@fda.hhs.gov.

Sincerely,

BLETA VUNIQI -S

Digitally signed by BLETA VUNIQI -S
Date: 2024.09.20 14:18:17 -04'00'

For,
Binita Ashar, M.D., M.B.A., F.A.C.S.
Director
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health