December 15, 2023

Steris Corporation
Logan Persons
Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K233681
Trade/Device Name: ConFirm 20 Minute Incubator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: November 16, 2023
Received: November 16, 2023

Dear Logan Persons:

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.

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.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233681

Device Name
ConFirm 20 Minute Incubator

Indications for Use *(Describe)*
Use the ConFirm 20 Minute Incubator to incubate and automatically read ConFirm Rapid 20 Minute Biological Indicators for Steam and Vaporized Hydrogen Peroxide sterilization at 55°C-60°C for a fluorescent result.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

STERIS®

510(k) Summary
For
ConFirm 20 Minute Incubator
K233681

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Mr. Logan Persons
Regulatory Affairs Specialist
Tel: 440-392-7325
Fax: 440-357-9198
Logan_persons@steris.com

Summary Date: December 15, 2023

1. Device Name

Trade Name:	ConFirm 20 Minute Incubator
Device Classification:	II
Common Name:	Incubator
Classification Name:	Indicator, Biological Sterilization Process
Classification Panel:	General Hospital and Personal Use Devices Panel
Classification Number:	21 CFR 880.2800
Product Code	FRC

2. Predicate Device

K223715 – Celerity Incubator

Reference Device
K173634 – ConFirm Biological Indicator (cleared as CELERITY 20 Steam Biological Indicator)

3. Device Description

The ConFirm 20 Minute Incubator incubates and reads fluorescent Vaporized Hydrogen Peroxide (VHP) and Steam Biological Indicators (BIs). The BI is incubated at 59°C with an acceptable tolerance of -4°C/+1°C. During incubation, the BI is monitored for a potential fluorescence signal generated as a result of the production of α-glucosidase. When a growth response has been detected or when the required incubation time has elapsed, the incubator indicates the results to the user.

4. Indications for Use

Use the ConFirm 20 Minute Incubator to incubate and automatically read ConFirm Rapid 20 Minute Biological Indicators for Steam and Vaporized Hydrogen Peroxide sterilization at 55°C-60°C for a fluorescent result.

5. Technological Characteristics Comparison Table

A comparison of technical characteristics between the proposed and predicate devices is summarized in **Table 1**.

Table 1. Technological Characteristics Comparison Table to predicate device

Feature	Modified Device ConFirm 20 Minute Incubator	Predicate Device Celerity Indicator (K223715)	Comparison
Indications for Use	Use the ConFirm 20	Use the Celerity Incubator	Same, only

Feature	Modified Device ConFirm 20 Minute Incubator	Predicate Device Celerity Indicator (K223715)	Comparison
	Minute Incubator to incubate and automatically read ConFirm Rapid 20 Minute Biological Indicators for Steam and Vaporized Hydrogen Peroxide sterilization at 55°C-60°C for a fluorescent result.	to incubate and automatically read STERIS Celerity Biological Indicators for Steam and Vaporized Hydrogen Peroxide sterilization at 55°C - 60°C for a fluorescent result.	change is branding of incubator and BI with which it is used
Basis of Readout	Photodiode detects fluorescence produced by enzymatic activity that results from viable biological indicator organisms.	Photodiode detects fluorescence produced by enzymatic activity that results from viable biological indicator organisms.	Same
Incubation Temperatur e Range	55 - 60 °C	55 - 60 °C	Same
Voltage Range	100-240 VAC with 12 VDC conversion	100-240 VAC with 12 VDC conversion	Same
Test Capacity	8 wells	8 wells	Same
Calibration	Factory calibration – no calibration by customer	Factory calibration – no calibration by customer	Same
Incubation Time	20 minutes	5 minutes or 20 minutes depending on Biological Indicator	Similar, the 5-minute BI is not being rebranded.
Fluorescenc e Detection	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the BI's media. The emitted light is detected by a photodiode.	UV LEDs are used to excite the fluorescent molecule produced by enzyme cleavage of the fluorogenic substrate contained in the BI's media. The emitted light is detected by a photodiode.	Same
Indication of Results	Positive – audible alarm, visual LED lights and	Positive – audible alarm, visual LED lights and	Same

Feature	Modified Device ConFirm 20 Minute Incubator	Predicate Device Celerity Indicator (K223715)	Comparison
	screen Negative – optional alarm, visual indication with LED lights and LCD screen User must acknowledge results	screen Negative – optional alarm, visual indication with LED lights and LCD screen User must acknowledge results	
System Operation	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 59ºC. The user scans the barcode on the label of an activated BI using the system's barcode scanner and places it into an open well. The system detects the well the BI was placed into and begins measurement of fluorescence; a blinking yellow light indicates the incubation is in process and the read initiated. The System uses information from the barcode to apply the appropriate algorithm to the well. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific BI.	The reader/incubator wells are arranged in 2 banks of 4 wells and preset to 59ºC. The user scans the barcode on the label of an activated BI using the system's barcode scanner and places it into an open well. The system detects the well the BI was placed into and begins measurement of fluorescence; a blinking yellow light indicates the incubation is in process and the read initiated. The System uses information from the barcode to apply the appropriate algorithm to the well. A "positive" reading is interpreted as an indication of a potential sterilization cycle failure. A "positive" finding is indicated to the user by red light on the front panel adjacent to the well, by an audible alarm, and by text displayed on the LCD screen. The alarm must be muted by the operator when a positive result is obtained. The LCD screen provides instructions for the user to turn off the alarm for that specific BI.	Same

Feature	Modified Device ConFirm 20 Minute Incubator	Predicate Device Celerity Indicator (K223715)	Comparison
	Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD. In addition, an optional alarm is available for negative results.	Should another BI become "positive", the alarm will sound again and the above actions are repeated. If the result is not positive at the end of the incubation time, the result is negative. Negative results are identified by a green light on the front panel adjacent to the well with the "negative" BI and by text on the LCD. In addition, an optional alarm is available for negative results.	

6. Summary of Non-Clinical Testing

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in **Table 2**.

Table 2. Performance Testing

Test	Acceptance Criteria	Result
Regression Testing	No unresolved anomalies	PASS

7. Conclusion

The ConFirm 20 Minute Incubator has met the established performance criteria. 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 the legally marketed predicate device (K223715), Class II (21 CFR 880.2800), product code FRC.