September 28, 2022

SteriCUBE, LLC
% Annette Hillring
President
Hillring & Associates, Inc.
3012 St. Charles Drive
Tampa, Florida 33618

Re: K222328
Trade/Device Name: SteriCUBE® Multiple Tray Sterilization Systems
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 29, 2022
Received: August 2, 2022

Dear Annette Hillring:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Colin O’Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K222328

Device Name
SteriCUBE(R) Multiple Tray Sterilization Systems

Indications for Use *(Describe)*

The SteriCUBE Multiple Tray Sterilization System (SteriCUBE System) is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SteriCUBE System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks.

The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

The SteriCUBE System was tested and validated with rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length longer than 500mm or lumens with an inner diameter smaller than 1.0mm and an overall length longer than 850mm.

Use only uncovered, perforated or wire mesh general delivery trays within the SteriCUBE System.

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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K222328 510(k) Summary

Submitter

SteriCUBE, LLC
2701 Beach Boulevard South
Gulfport, FL 33707

Contact person: Michele E. Mauzerall, CEO
Phone: 908-300-7093
Email: mem.pmbs@gmail.com

Date prepared: September 27, 2022

Device

SteriCUBE® Multiple Tray Sterilization Systems

Predicate Device

MTS225 and MTS300 Multiple Tray Sterilization Systems ("MTS Systems") cleared most recently November 5, 2019, via K190541

Device Description

The SteriCUBE® Multiple Tray Sterilization Systems are also referred to as the "SteriCUBE Systems" and include the SteriCUBE MTS225 System and the SteriCUBE MTS300 System. The SteriCUBE System is comprised of the stainless steel sterilization cabinet and adjustable transfer cart. An optional reusable ceramic drain filter and single use filters and integrity locks with sterilization indicator dots are used with the system for each sterilization cycle. The optional ceramic drain filter should be replaced every 6 months or after 160 uses, whichever comes first. An optional STEAMPlus™ tray record card with STEAMPlus sterilization integrator (SPS Medical) may be utilized by the healthcare provider.

Adjustable shelves within the cabinet can hold up to three trays (uncovered, perforated or wire mesh) of devices and/or surgical instruments intended for a single patient surgery. No more than 25 pounds can be loaded per tray for a maximum of 75 pounds per shelf. The MTS300 Cabinet (with four shelves) can hold up to 300 pounds per load and the MTS225 Cabinet (with three shelves) can hold up to 225 pounds per load.

The loaded cabinet is deployed from the adjustable transfer cart and processed in pre-vacuum steam sterilizers. Processing includes the standard conditioning phase of the autoclave followed by a sterilization cycle time of 4 minutes and a dry cycle of a minimum of 5 minutes. Sterility is maintained for up to 30 days.

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Section 5: 510(k) Summary, continued

Indications for Use

The SteriCUBE Multiple Tray Sterilization System (SteriCUBE® System) is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SteriCUBE System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks.

The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray.

The SteriCUBE System was tested and validated with rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length longer than 500mm or lumens with an inner diameter smaller than 1.0mm and an overall length longer than 850mm.

Use only uncovered, perforated or wire mesh general delivery trays within the SteriCUBE System.

Comparison of Technological Characteristics with the Predicate Device

There are no new technological characteristics associated with the modified SteriCUBE System. A comparison of the technological characteristics of the subject device, the SteriCUBE System (SteriCUBE MTS225 and SteriCUBE MTS300 Systems) to the predicate, the currently marketed MTS225 and MTS300 Systems, is provided in the table on the following pages.

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Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: SteriCUBE® Systems (SteriCUBE MTS225 and SteriCUBE MTS300 Systems)	Predicate Device: MTS225 and MTS300 Systems (K190541)
Indications for Use	The SteriCUBE Multiple Tray Sterilization System is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the SteriCUBE System Transfer Cart, SteriCUBE System Filters and SteriCUBE System Integrity Locks. The SteriCUBE System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray. The SteriCUBE System was tested and validated with rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length longer than 500mm or lumens with an inner diameter smaller than 1.0mm and an overall length longer than 850mm. Use only uncovered, perforated or wire mesh general delivery trays within the SteriCUBE System.	The MTS System (Multiple Tray Sterilization System) is indicated for enclosing other medical devices that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed materials and maintain sterility for up to 30 days until used. The unit must be used with the MTS System Transfer Cart, MTS System Filters and MTS System Integrity Locks. The MTS System is intended to be used in prevacuum steam sterilizers with a prevacuum cycle of 270°F and exposure time of 4 minutes. Use no more than 3 trays per shelf or 25 lbs. per tray. The MTS System was tested and validated with rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm. Do not use with instruments containing lumens with an inner diameter smaller than 0.7mm and an overall length longer than 500mm or lumens with an inner diameter smaller than 1.0mm and an overall length longer than 850mm. Use only uncovered, perforated or wire mesh general delivery trays within the MTS System.
Sterilization Parameters	Prevacuum cycle of 270ºF and exposure time of 4 minutes	Prevacuum cycle of 270ºF and exposure time of 4 minutes
Minimum Drying Time	5 minutes	10 minutes

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Section 5: 510(k) Summary, continued

Comparison of Technological Characteristics with the Predicate Device, continued

Characteristic	Subject Device: SteriCUBE Systems (SteriCUBE MTS225 and SteriCUBE MTS300 Systems)	Predicate Device: MTS225 and MTS300 Systems (K190541)
Sterility Maintenance	30 days	30 days
Cabinet Material	16 gauge stainless steel	16 gauge stainless steel
Weight w/ Shelves	212 lbs (MTS300) and 185 lbs (MTS225)	212 lbs (MTS300) and 185 lbs (MTS225)
Filter Material	Heavy duty sterilization wrap by SPS Medical Optional ceramic drain filter Optional sterilization wrap filter separators	Heavy duty sterilization wrap by SPS Medical
Volume-to-Vent Ratio	129.131 (MTS300) and 94.725 (MTS225)	129.131 (MTS300) and 94.725 (MTS225)
Deployment into Sterilization Chamber	Adjustable transfer cart	Adjustable transfer cart
Recommended Sterilization Trays	All manufacturers' trays – uncovered, perforated or wire mesh general delivery trays	All manufacturers' trays – uncovered, perforated or wire mesh general delivery trays
Recommended Sterilizers	All makes and models with dimensions compatible with the SteriCUBE System	All makes and models with dimensions compatible with the MTS System

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Section 5: 510(k) Summary, continued

Comparison of Technological Characteristics with the Predicate Device, continued

Modifications introduced into the SteriCUBE® Multiple Tray Sterilization Systems do not affect the technological characteristics. The cabinet material remains stainless steel and a filtration system utilizing disposable paper filters of the same material from the same supplier is the method by which sterilization is achieved and maintained. The optional reusable drain ceramic filter and paper filter separators are available for user convenience and performance data confirms their effectiveness. The cabinet continues to be deployed into the sterilization chamber with an adjustable transfer cart. The sterilization parameters and sterility maintenance specifications are identical to the predicate device.

The SteriCUBE Systems (both the SteriCUBE MTS225 and MTS300 Systems) have demonstrated the ability to:

- achieve a 10^{-6} SAL when sterilizing longer and smaller lumen sized instruments (rigid instruments containing lumens with an inner diameter of 0.7mm and an overall length of 500mm as well as lumens with an inner diameter of 1.0mm and an overall length of 850mm),
- meet the shorter minimum dry time of 5 minutes, and
- maintain sterility for 30 days.

Performance Data

Nonclinical data was generated to ensure the SteriCUBE System continues to meet the intended use. Sterilization efficacy verification studies were performed in accordance with the appropriate requirements of ANSI/AAMI ST77:2013 *Containment devices for reusable medical device sterilization*.

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR 807, and based upon the information and scientifically valid data provided in this premarket notification, SteriCUBE, LLC, concludes that the subject device, the SteriCUBE Systems (SteriCUBE MTS225 and MTS300 Systems) is as safe, as effective and perform as well as the predicate device, the MTS225 and MTS300 Multiple Tray Sterilization Systems (K190541).