August 1, 2022

Consolidated Machine Corp.
Arthur Trapotsis
CEO
3 Enterprise Rd, Suite C
Billerica, Massachusetts 01821

Re: K220736
Trade/Device Name: Consolidated HC Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: June 28, 2022
Received: June 30, 2022

Dear Arthur Trapotsis:

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,

Clarence W. Murray, III, PhD
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220736

Device Name
Consolidated HC Steam Sterilizer

Indications for Use *(Describe)*

The Consolidated HC Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities using saturated steam as the sterilizing agent. They are equipped with factory programmed cycles. The factory programmed cycles, the chamber and overall dimensions, and the number of standard test items per AAMI ST8:2013 R2018 for all models of the HC Series steam sterilizers are provided below.

Table 1: Validated Sterilization Cycles

Cycle Type	Sterilization Temperature	Sterilization Time	Dry Time	Load Type
Gravity	250°F (121°C)	30 minutes	30 minutes	Fabric Packs
Gravity	250°F (121°C)	30 minutes	30 minutes	Double Wrapped Instrument Trays Maximum weight per tray: 25lbs (11.3 kg)
Gravity – IUSS	270°F (132°C)	3 minutes	1 minutes	Single Unwrapped Tray Maximum weight per tray: 25lbs (11.3 kg)
Gravity	270°F (132°C)	15 minutes	30 minutes	Double Wrapped Instrument Trays Maximum weight per tray: 25lbs (11.3 kg)
Pre-Vacuum – IUSS	270°F (132°C)	4 minutes	1 minutes	Single Unwrapped Tray Maximum weight per tray: 25lbs (11.3 kg)
Pre-Vacuum	270°F (132°C)	4 minutes	20 minutes	Fabric Packs
Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes	Double Wrapped Instrument Trays Maximum weight per tray: 25lbs (11.3 kg)
Pre-Vacuum	275°F (135°C)	3 minutes	30 minutes	Double Wrapped Instrument Trays Maximum weight per tray: 25lbs (11.3 kg)
Pre-Vacuum	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack and Single Unwrapped Tray Maximum weight per tray: 25lbs (11.3 kg)

Table 1 (cont.): Validated Sterilization Cycles

Liquids	250°F (121°C)	30 minutes	N/A	1L Liquid Volumes
Bowie Dick Test	273°F (134°C)	3.5 minutes	0 minutes	Bowie Dick Test Pack
Vacuum Leak Test	270°F (132°C)	N/A	N/A	Empty Chamber
Warm Up	270°F (132°C)	3 minutes	1 minutes	Empty Chamber

Table 2: Load Size

Model	Sterilizer Chamber Size	Double Wrapped Instrument Trays[1]	Fabric Packs[2]	Number of Liquid Containers[3]
26AV-HC	26” X 26” X 39”	9, maximum weight 25lb each	12	70, 1 Liter Volume Per Container
26BV-HC	26” X 26” X 49”	12, maximum weight 25lb each	16	90, 1 Liter Volume Per Container
3AV-HC	20” X 20” X 38”	3, maximum weight 25lb each	9	28, 1 Liter Volume Per Container

1 For instrument trays, the maximum weight per tray is 25lbs (11.3 kg).
2 The weight of each fabric pack should be limited to approximately 3.2 lbs (1.4 kg) with a density of 11.3 lb/ft3 (181 kg/m3) or less.
3 For liquid containers, the maximum volume of liquid per container is 1,000 ml. Please note, liquid loads processed in the sterilizer are inappropriate for direct patient contact.

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 for Consolidated HC Steam Sterilizer

Consolidated Sterilizer Systems
3 Enterprise Road, Suite C
Billerica, MA 01821

Contact: Arthur Trapotsis
Phone: 617-782-6072 ext2200
Email: Arthur@consteril.com

Premarket Notification Number: K220736
Date of Preparation: July 27, 2022

Device Name

Trade Name:	Consolidated HC Steam Sterilizer
Device Class:	Class II
Common Name:	Steam Sterilizer/Autoclave
Classification Name:	Sterilizer, Steam
Classification Number:	21 CFR 880.6880
Product Code:	FLE

Predicate Device

K183410 AMSCO 600 Steam Sterilizer

Device Class:	Class II
Common Name:	Steam Sterilizer/Autoclave
Classification Name:	Sterilizer, Steam
Classification Number:	21 CFR 880.6880
Product Code:	FLE

Description of Device

The steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical products by means of pressurized steam (reference 21 CFR Part 880.6880). Three models have been selected for the Consolidated HC Sterilizer product line: Model 3AV-HC, Model 26AV-HC, and Model 26BV-HC. The sterilizer will be targeted for sale into Ambulatory Surgery Centers (ASCs), Clinics, and Hospitals.

The Consolidated HC Steam Sterilizers are for general purpose gravity, vacuum, or liquid steam sterilization of heat and moisture-stabile medical goods, surgical instruments, and supplies. All models utilize both gravity/downward air displacement with positive-pressure pulse conditioning and pressure/vacuum pulsing for dynamic air removal. The programmed cycles are easily accessed and are password protected. All cycle phases are sequenced and monitored by a PLC-based control system, providing both audible and visual notification of deviation from critical operating parameters. These sterilizers can either be supplied for connection to direct building steam supply of 50-80 PSI of steam pressure or come equipped with an integral, electrically heated steam generator.

Indications for Use

The Consolidated HC Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities using saturated steam as the sterilizing agent. They are equipped with factory programmed cycles. The factory programmed cycles, the chamber and overall dimensions, and the number of standard test items per AAMI ST8:2013 R2018 for all models of the HC Series steam sterilizers are provided below.

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Cycle Type	Sterilization Temperature	Sterilization Time	Dry Time	Load Type
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Pre-Vacuum	270°F (132°C)	4 minutes	20 minutes	Fabric Packs
Pre-Vacuum	270°F (132°C)	4 minutes	30 minutes	Double Wrapped Instrument Trays Maximum weight per tray: 25lbs (11.3 kg)
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Liquids	250°F (121°C)	30 minutes	N/A	1L Liquid Volumes
Bowie Dick Test	273°F (134°C)	3.5 minutes	0 minutes	Bowie Dick Test Pack
Vacuum Leak Test	270°F (132°C)	N/A	N/A	Empty Chamber
Warm Up	270°F (132°C)	3 minutes	1 minutes	Empty Chamber

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Model	Sterilizer Chamber Size	Double Wrapped Instrument Trays[1]	Fabric Packs[2]	Number of Liquid Containers[3]
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1 For instrument trays, the maximum weight per tray is 25lbs (11.3 kg).
2 The weight of each fabric pack should be limited to approximately 3.2 lbs (1.4 kg) with a density of 11.3 lb/ft3 (181 kg/m3) or less.
3 For liquid containers, the maximum volume of liquid per container is 1,000 ml. Please note, liquid loads processed in the sterilizer are inappropriate for direct patient contact.

Technological Characteristics

Table 3: Comparison of the Proposed Device and the Predicate Device

Feature	Consolidated HC Steam Sterilizer	AMSCO 600 Steam Sterilizer (K183410)	Comparison
Intended Use	The sterilization of heat and moisture-stable materials used in healthcare facilities.	The sterilization of heat and moisture-stable materials used in healthcare facilities.	Same
Critical Process Parameters	Time, Chamber Temperature, Pressure	Time, Chamber Temperature, Pressure	Same
Control	Programmable Logic Controller	Embedded Controller	Different
SAL	10^{-6}	10^{-6}	Same
Sterilant	Saturated Steam	Saturated Steam	Same
Utilities	Steam, Water, Electricity, Air	Steam, Water, Electricity, Air	Same
Chamber Material	316L Stainless Steel	316L Stainless Steel	Same
Nominal Chamber Size	26" X 26" X 39" 26" X 26" X 49" 20" X 20" X 38"	26" X 26" X 39" 26" X 26" X 49"	Similar
Door	316L Stainless Steel 26" X 26" Power Vertical Sliding 20" X 20" Power Vertical Sliding	304L Stainless Steel 26" X 26" Power Vertical Sliding	Similar
Chamber Pressure Rating	45 psig, 300 °F	45 psig, 300 °F	Same
Door Seal	Air Activated Door Seal	Steam Activated Door Steam	Similar
External Process Monitors	Electronic Control Printer	Electronic Control Printer	Same

Internal Process Monitors	RTD temperature sensor in chamber drain RTD temperature sensor in jacket drain RTD temperature sensor in waste drain Pressure transducer in chamber	RTD temperature sensor in chamber drain RTD temperature sensor in jacket drain RTD temperature sensor in heat exchanger Pressure transducer in chamber	Same
Performance	Meets ANSI/AAMI ST8:2013 (R)2018	Meets ANSI/AAMI ST8:2013	Similar
Accessories	Shelves, Loading Equipment	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment	Different
Test Cycles	Warm Up, Leak Test, Bowie Dick Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same
Cycles	See Table 1	270°F, Prevac, 4 min, Full fabric pack 270°F, Prevac, 4 min, Full tray 270°F, Prevac, 4 min, one fabric pack 270°F, Prevac, 4 min, IUSS 275°F, Prevac, 4 min, Full fabric pack 250°F, Gravity, 30 min, Full tray	Similar
Full Loads	26AV: 9, 25 lb double wrapped trays or 12 fabric packs 26BV: 12, 25 lb double wrapped trays or 16 fabric packs 3AV: 3, 25 lb double wrapped trays or 6 fabric packs	39”: 9, 25 lb double wrapped trays or 12 fabric packs 49”: 12, 25 lb double wrapped trays or 16 fabric packs	Similar

The proposed device has the same intended use, instructions for use, and meets the same performance specification as the predicate device. The proposed device has similar technological characteristics as the predicate device. The proposed device offers more validated sterilization cycles than the predicate device. The proposed device offers an additional chamber size.

Non-Clinical Tests

The Consolidated HC Steam Sterilizer non-clinical testing was performed according to the following standards, with passing results in all cases:

Table 4: Non-Clinical Test Results

Test	Acceptance Criteria	Result
Performance	Meets requirements of AAMI ST8: 2013/(R)2018	Pass
General Electrical Safety	Meets requirements of UL 61010-1, 3rd Edition	Pass
Sterilizer Electrical Safety	Meets requirements of UL 61010-2-040	Pass
Electromagnetic Compatibility	Meets requirements of IEC 61326-1:2020, FCC Part 15 subpart b, and Table 9 Per IEC 60601-1-2:2014	Pass
Pressure Vessel Safety	Meets requirements of Section VIII, ASME Boiler & Pressure Vessel Code, 2019	Pass
Generator Safety	Meets requirements of Section I, ASME Boiler & Pressure Vessel Code, 2019	Pass

The testing demonstrated that the subject devices, 3AV-HC, 26AV-HC, and 26BV-HC, met the acceptance criteria described in these standards.

Clinical Tests

No clinical testing was used in support of this submission.

Conclusion

The conclusions drawn from the nonclinical performance data demonstrate that the device, the Consolidated HC Steam Sterilizer, is as safe, as effective, and performs as well as or better than the legally marketed predicate device, K183410.