August 25, 2021

Steris Corporation
Anthony Piotrkowski
Director, Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K211500
Trade/Device Name: AMSCO 600 Medium Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: June 2, 2021
Received: June 3, 2021

Dear Anthony Piotrkowski:

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, Ph.D.
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)*

K211500

Device Name

AMSCO 600 Steam Sterilizer

Indications for Use *(Describe)*

The AMSCO 600 Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are equipped with the following factory-programmed cycles (Table 1):

Table 1. AMSCO 600 Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Maximum Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each and Fabric Packs. *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	10 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each . *Refer to Table 2 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack.
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. *Refer to Table 2 for recommended quantities.*
Prevac-IUSS	270°F (132°C)	4 minutes	1 minutes	Immediate use – single unwrapped tray
Gravity	250°F (121°C)	30 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. *Refer to Table 2 for recommended quantities.*
Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3.5 minutes	1 minute	Bowie-Dick Test Pack, DART
Leak Test	N/A	N/A	N/A	N/A

Table 2 AMSCO 600 Steam Sterilizer full load per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26” x 26” x 39”	9	12
26” x 26” x 51”	12	16
26” x 26” x 63”	15	20

The Automated Load and Unload System (ALUS) provides semi-automated loading and unloading from an AMSCO 600 steam sterilizer when a cycle is complete. Alternatively, the ALUS may also be used to provide automatic unloading only in combination with manual loading. The ALUS can start a cycle automatically when equipped with the optional bar code reader.

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
AMSCO 600 Steam Sterilizer
K211500

STERIS Corporation
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Phone: (440) 354-2600
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Contact: Tony Piotrkowski
Director, Regulatory Affairs

Telephone: (440) 392-7437
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Summary Date: August 23, 2021

Premarket Notification Number: K211500

1. Device Name

Trade Name:	AMSCO 600 Steam Sterilizer
Device Class:	Class II
Common/usual Name:	Steam Sterilizer
Classification Name:	Sterilizer, Steam Sterilizer Automated Loading System
Classification Number:	21 CFR 880.6880
Product Code:	FLE, PEC

2. Predicate Device

K183410 AMSCO 600 Steam Sterilizer

3. Description of Device

The AMSCO 600 Steam Sterilizer uses saturated steam, generated from a house steam utility (e.g. boiler system) or from a steam generator, to sterilize heat-stable health care products.

The sterilizer accomplishes this by removing the air in the chamber, exposing the load to saturated steam for a defined combination of time and temperature, and drying the load. Removal of air from the chamber occurs using either of two methods, gravity displacement or mechanical vacuum. Once the air removal phase is completed, the sterilizer progresses to the steam exposure phase. During the steam exposure phase, every surface of the load is exposed to saturated steam for a defined combination of time and temperature. Once the steam exposure phase is completed, steam is removed from the chamber and the load is dried using the latent heat in the load and the vacuum pump.

The sterilizers are generally operated by technicians in a central service or sterile processing department of healthcare facilities. Sterilizers may also be located in a surgical suite to allow for Immediate Use Steam Sterilization (IUSS) for instances where an instrument is needed immediately for a procedure (e.g. after an instrument has been dropped and there is no replacement readily available). Standard practices for use of sterilizers in health care facilities are provided by various organizations (e.g. ANSI/AAMI ST79).

The ALUS is used with the AMSCO 600 Steam Sterilizer's existing transfer carriages and loading carts. It consists of a conveyor system which attaches to the

load and/or unload ends of the steam sterilizer. It has a series of barcode labels which correspond to pre-programmed cycles and an optional scanner which when fitted to the system will communicate to the sterilizer which cycle to initiate.

4. Intended Use/Indications for Use

The AMSCO 600 Steam Sterilizers are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are equipped with the following factory-programmed cycles (Table 1):

Table 1. AMSCO 600 Steam Sterilizer factory-validated sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Maximum Recommended Load
Prevac	270°F (132°C)	4 minutes	20 minutes	Fabric Packs. *Refer to Table 2 for recommended quantities.*
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The Automated Load and Unload System (ALUS) provides semi-automated loading and unloading from an AMSCO 600 steam sterilizer when a cycle is complete. Alternatively, the ALUS may also be used to provide automatic unloading only in combination with manual loading. The ALUS can start a cycle automatically when equipped with the optional bar code reader.

5. Technological Characteristics Comparison

Table 5-1. Device Comparison Table for AMSCO 600 Modified and Predicate

Feature	AMSCO 600 Steam Sterilizer (Modified Device)	AMSCO 600 Steam Sterilizer (Predicate Device/K183410)	Comparison
Intended Use	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	The AMSCO 600 Steam Sterilizer is designed for 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	Embedded Controller	Embedded Controller	Same
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” w x 26” h x 39” d • 26” w x 26” h x 49” d • 26” w x 26” h x 61” d	• 26” w x 26” h x 39” d • 26” w x 26” h x 49” d 26” w x 26” h x 61” d	Same
Door	304L Stainless Steel 26” x 26” Power vertical sliding	304L Stainless Steel 26” x 26” Power vertical sliding	Same
Chamber Pressure Rating	45 psig, 300°F	45 psig, 300°F	Same
Door Seal	Steam activated door seal	Steam activated door seal	Same
External Process Monitors	• Electronic Control • Printer	• Electronic Control • Printer	Same
Internal Process Monitors	**Temperature** -Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in heat exchanger **Pressure** -Pressure transducer in chamber	**Temperature** -Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in heat exchanger **Pressure** -Pressure transducer in chamber	Same
Performance	Meets ANSI/AAMI ST8:2013	Meets ANSI/AAMI ST8:2013	Same
Accessories	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment, automated loading system	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment	Added automated loading system. Software validation demonstrates proper performance
Test Cycles	Warm Up, Leak Test, DART (Bowie Dick) Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same

Feature	AMSCO 600 Steam Sterilizer (Modified Device)	AMSCO 600 Steam Sterilizer (Predicate Device/K183410)	Comparison
Cycles	270F, Prevac, 4' Full fabric pack 270F, Prevac, 4' Full tray 270F, Prevac, 4' One fabric pack 270F, Prevac, 4' IUSS 275F, Prevac, 3' Full fabric 250F, Gravity, 30' Full tray 270F, Prevac, 10' Full tray	270F, Prevac, 4' Full fabric pack 270F, Prevac, 4' Full tray 270F, Prevac, 4' One fabric pack 270F, Prevac, 4' IUSS 275F, Prevac, 3' Full fabric 250F, Gravity, 30' Full tray	Added 10-minute 270F, prevacuum cycle. Testing performer per AAMI ST8 demonstrates proper performance
Full Loads	• 39": 9, 25-lb double wrapped trays or 12, fabric packs • 51": 12, 25-lb double wrapped trays or 16, fabric packs • 63": 15, 25-lb double wrapped trays or 20, fabric packs	• 39": 9, 25-lb double wrapped trays or 12, fabric packs • 51": 12, 25-lb double wrapped trays or 16, fabric packs • 63": 15, 25-lb double wrapped trays or 20, fabric packs	Same

The proposed device has the same intended use as the predicate with the same technological characteristics. The modifications, subject of this submission, are addition a 10-minute, 270 °F (132 °C) prevacuum, steam sterilization cycle and addition of an automated loading and unloading system (ALUS). Sterilizer automated loading systems are described under FDA product code PEC so the resulting product will be under product codes FLE and PEC. Other design modifications since the last clearance have been made to improve manufacturability, allow for sale outside the United States and add convenience features to sterilizer.

6. Summary of Nonclinical Tests

Test	Criterion	Results
Sterilizer performance	Meets ST 8 requirements: Temperature distribution: - 0 to + 6 °F Air removal – CI pass, 270 -276 °F Moisture retention – ≤ 20% mass increase Biological performance – $F_0 \geq 12$, BI pass	 0 to + 4.3 °F CI pass, 271 - 273 °F ≤ 16 % mass increase $F_0 \geq 87$, BI pass
Electrical safety	Meets IEC 61010-1:2012, IEC 61010-2-040:2016 and IEC 61326-1:2012 requirements for electrical safety	Conforms with: IEC 61010-1:2012 IEC 61010-2-040:2016 IEC 61326-1:2012
Software validation	Meets documented software specifications	Software meets specifications
ALUS Function	Meets documented performance specifications	Properly loads and unloads

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device K183410, Class II (21 CFR 880.6860), product code FLE.