March 27, 2019

STERIS Corporation
Anthony Piotrkowski
Director of Regulatory Affairs
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K183410
Trade/Device Name: AMSCO 600 Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: March 1, 2019
Received: March 4, 2019

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 III -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183410

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)	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 Test Pack
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
26.5” x 26.5” x 39”	9	12
26.5” x 26.5” x 51”	12	16
26.5” x 26.5” x 63”	15	20

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

STERIS Corporation
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Contact: Tony Piotrkowski
Director, Regulatory Affairs

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e-mail: Tony_Piotrkowski@steris.com

Summary Date: March 1, 2019

Premarket Notification Number: K183410

1. Device Name

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

2. Predicate Device

K112403 AMSCO Chimeron Steam Sterilizer (later renamed AMSCO 400)

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).

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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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 Test Pack
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
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26.5” x 26.5” x 63”	15	20

5. Technological Characteristics

Table 3. Technological Characteristics Comparison Table for AMSCO 600 and AMSCO Chimeron

Feature	AMSCO 600 Steam Sterilizer (K183410)	AMSCO Chimeron Steam Sterilizer (Predicate Device/K112403)	Comparison
Intended Use	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	The AMSCO Chimeron Medium Steam Sterilizer (Models 39SL and 39CSL) are 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	Proposed offered in additional sizes, all validated per ANSI/AAMI ST8
Door	304L Stainless Steel 26” x 26” Power vertical sliding	316L Stainless Steel 26” x 26” Power vertical sliding	Both stainless steel, same operation
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

Feature	AMSCO 600 Steam Sterilizer (K183410)	AMSCO Chimeron Steam Sterilizer (Predicate Device/K112403)	Comparison
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 ST8:2006	Proposed sterilizer meets current revision of the sterilizer standard
Accessories	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment	Same

Test Cycles	Warm Up, Leak Test, DART (Bowie Dick) Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same
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, 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 250F, Gravity, 30' Full fabric 270F, Gravity, 15' Full tray 270F, Gravity, 25' Full fabric 270F, Gravity, 3' IUSS 270F, Gravity, 10' IUSS 250F, Liquid, 45', 80-1L bottles	All cycles available on the proposed sterilizer were also available on the predicate
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	4, 25-lb double wrapped trays or 12, fabric packs	Proposed sterilizer can sterilize larger loads – maximum load configurations validated per ANSI/AAMI ST8

The proposed device has the same intended use and similar indications for use as the predicate with similar technological characteristics. The subject device slightly differ in their design and indications and features to the predicate device.

6. Summary of Nonclinical Tests

The AMSCO 600 Steam Sterilizer nonclinical test was performed according to the standards described below in Table 4. The testing demonstrated that subject device met the acceptance criteria described in these standards.

Table 4: Non-Clinical Testing of AMSCO 600 Steam Sterilizer

Test	Result	Conclusion
Performance	Meets requirements of ANSI/AAMI ST8	PASS
General Electrical Safety	Meets requirements of IEC 61010-1	PASS
Sterilizer Electrical Safety	Meets requirements of IEC 61010-2-40	PASS
Electromagnetic Compatibility	Meets requirements of FCC 47 CFR Part 15 - Subpart B	PASS
Pressure Vessel Safety	Meets requirements of ASME *Boiler Pressure Vessel Code*, Section VIII (Division 1)	PASS

7. 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 or better than the legally marketed predicate device K112403, Class II (21 CFR 880.6860), product code FLE.