June 24, 2026

STERIS Corporation
Karly Eitzman
Regulatory Affairs Specialist
5960 Heisley Rd.
Mentor, Ohio 44060

Re: K261055
Trade/Device Name: AMSCO 700 Steam Sterilizer
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE, PEC
Dated: March 31, 2026
Received: March 31, 2026

Dear Karly Eitzman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

STEPHEN A. ANISKO -S
Digitally signed by STEPHEN A. ANISKO -S
Date: 2026.06.24 19:55:49 -04'00'

Stephen Anisko
Acting Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K261055

Device Name
AMSCO 700 Steam Sterilizer

Indications for Use *(Describe)*
The AMSCO 700 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. AMSCO 700 Steam Sterilizer 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. See Table 2 for maximum 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	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-IUSS	270°F (132°C)	4 minutes	1 minute	Immediate use – single unwrapped tray
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs. (11.3 kg) each. Refer to Table 2 for recommended quantities.
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

The maximum quantities of wrapped instrument trays or fabric packs for each proposed model are as follows:

Table 2. AMSCO 700 Steam Sterilizer maximum 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 700 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 700 Steam Sterilizer
K261055

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

Contact: Karly Eitzman
Regulatory Affairs Specialist
Phone: (440) 514-4512
Email: Karly_Eitzman@steris.com

Summary Date: March 31, 2026

1. Device Name

Trade Name:	AMSCO 700 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

K232485 AMSCO 600 Steam Sterilizer

3. Description of Device

The AMSCO 700 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 Automated Load and Unload System (ALUS) is used with the AMSCO 700 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 700 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. AMSCO 700 Steam Sterilizer sterilization cycles and cycle values

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5. Technological Characteristics Comparison

Table 3. Device Comparison Table for the AMSCO 700 Steam Sterilizer and the predicate device, the AMSCO 600 Steam Sterilizer

Feature	Predicate Device (K232485) AMSCO 600 Steam Sterilizer	Proposed Device AMSCO 700 Steam Sterilizer	Comparison
Intended Use	The AMSCO 600 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	The AMSCO 700 Steam Sterilizer is designed for sterilization of heat and moisture-stable materials used in healthcare facilities.	Same, except for model number
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 51" d • 26" w x 26" h x 63" d	• 26" w x 26" h x 39" d • 26" w x 26" h x 51" d • 26" w x 26" h x 63" d	Same
Door	304L Stainless Steel 26" x 26" Power vertical sliding	316L Stainless Steel 26" x 26" Power vertical sliding, assisted by counterweights	Similar, Grade of stainless steel and door control assist differs
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 mixing tank **Pressure** - Pressure transducer in chamber	**Temperature** - Dual element RTD located in chamber drain - RTD located in the jacket drain - RTD located in mixing tank **Pressure** - Pressure transducer in chamber	Same
Performance	Meets ANSI/AAMI ST8:2013	Meets ANSI/AAMI ST8:2013(R)2018	Same, standard was reaffirmed in 2018
Accessories	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment, automated loading system	BI, CI, Pouches, Trays, Wraps, Tape, Containers, Shelves, Loading Equipment, automated loading system	Same
Test Cycles	Warm Up, Leak Test, DART (Bowie Dick) Test	Warm Up, Leak Test, DART (Bowie Dick) Test	Same
Cycles	270°F, Prevac, 4' Full fabric pack	270°F, Prevac, 4' Full fabric pack	Same,

Feature	Predicate Device (K232485) AMSCO 600 Steam Sterilizer	Proposed Device AMSCO 700 Steam Sterilizer	Comparison
	270°F, Prevac, 4' Full tray 270°F, Prevac, 4' One fabric pack 270°F, Prevac, 4' IUSS 275°F, Prevac, 3' Full fabric 250°F, Gravity, 30' Full tray 270°F, Prevac, 10' Full tray	270°F, Prevac, 4' Full tray 270°F, Prevac, 4' One fabric pack 270°F, Prevac, 4' IUSS 275°F, Prevac, 3' Full fabric 270°F, Gravity, 15' Full tray 250°F, Gravity, 30' Full tray 270°F, Prevac, 10' Full tray	except for additional Gravity cycle at 270°F
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, conditions of use, and principles of operation as the predicate. Although there are minor differences in technological characteristics, they do not raise different concerns of safety or effectiveness, and the provided performance test methods and performance data demonstrate the performance of the proposed device to achieve the intended use is equivalent to the predicate.

6. Summary of Nonclinical Tests

Table 4. Summary of Nonclinical Tests

Test	Acceptance Criteria	Conclusion
Sterilizer Performance	Meets requirements of ANSI/AAMI ST8	Pass
Pressure Vessel Safety	Meets requirements of ASME Boiler and Pressure Vessel Code, VIII – Div. 1	Pass
General Electrical Safety	Meets requirements of IEC 61010-1	Pass
Sterilizer Electrical Safety	Meets requirements of IEC 61010-2-040	Pass
Electromagnetic Compatibility	Meets requirements of IEC 60601-1-2 with IEC TS 60601-4-2	Pass
Software Validation	Meets requirements of IEC 62304	Pass

7. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the AMSCO 700 Steam Sterilizer is as safe, as effective and performs as well or better than the legally marketed predicate device, the AMSCO 600 Steam Sterilizer (K232485), Class II (21 CFR 880.6860), product code FLE.