February 22, 2018

STERIS Corporation
Anthony Piotrkowski
Senior Manager Regulatory Affairs
5960 Heisley Rd
Mentor, Ohio 44060

Re: K173490
Trade/Device Name: Amsco Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)
Regulation Number: 21 CFR 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: Class II
Product Code: FLE
Dated: December 12, 2017
Received: December 26, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael J. Ryan -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)*

K173490

Device Name

Amsco Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)

Indications for Use *(Describe)*

The Amsco Evolution Medium Steam Sterilizer Models HC-800 and HC-1000 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- Prevacuum – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- Steam Flush Pressure-Pulse (SFPP) – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The Amsco Evolution Medium Prevacuum Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 5-1):

Table 5-1. Amsco Evolution Medium Prevacuum Steam Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
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 5-3 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 5-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 5-4 for recommended quantities.*
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-3 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 5-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 5-3 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

* The liquid cycle is for non-patient contact use only.

The Amsco Evolution Medium Steam Flush Pressure-Pulse (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 5-2):

Table 5-2. Amsco Evolution Medium Steam Flush Pressure-Pulse (SFPP) Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	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 5-3 for recommended quantities.*
SFPP	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-3 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 5-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 5-3 for recommended quantities.*
SFPP	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 5-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 5-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 5-4 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

Table 5-3. Amsco Evolution Medium Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 26" x 49"	12	16
26" x 26" x 61"	15	20

The following table is a guideline for liquid cycle processing:

Table 5-4. Amsco Evolution Medium Steam Sterilizer Liquid Cycle Guideline

Number of Containers	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250ºF (121ºC)
3	1000 ml	45 minutes

The Amsco Evolution Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 26" x 49" (Model HC – 800)
- 26" x 26" x 61" (Model HC – 1000)

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 Evolution Medium Steam Sterilizer

STERIS Corporation
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Submission Date: February 12, 2018

Premarket Notification Number: K173490

1. Device Name

Trade Name: Amsco® Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)

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

AMSCO Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000), K091731.

3. Description of Device

The Amsco Evolution Medium Steam Sterilizer models HC-800 and HC-1000 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The chamber sizes of the proposed Amsco Evolution Medium Steam Sterilizer Models are as follows:

- 26" x 26" x 42" (Model HC – 800)
- 26" x 26" x 54" (Model HC – 1000)

4. Intended Use

The Amsco Evolution Medium Steam Sterilizer Models HC-800 and HC-1000 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

- *Prevacuum* – is equipped with Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.
- *Steam Flush Pressure-Pulse (SFPP)* – is equipped with SFPP, Prevacuum, Gravity, Liquid, Leak Test and DART (Bowie-Dick) cycles.

The Amsco Evolution Medium *Prevacuum* Steam Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 6-1):

Table 6-1. Amsco Evolution Medium *Prevacuum* Steam Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
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 6-3 for recommended quantities.*
Prevac	270°F (132°C)	4 minutes	5 minutes	Single Fabric Pack
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 6-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 6-4 for recommended quantities.*
Prevac	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 6-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 6-3 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 6-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 6-3 for recommended quantities.*
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

**The liquid cycle is for non-patient contact use only.*

The Amsco Evolution Medium *Steam Flush Pressure-Pulse* (SFPP) Sterilizer is equipped with the following factory-programmed sterilization cycles and cycle values (Table 6-2):

Table 6-2. Amsco Evolution Medium *Steam Flush Pressure-Pulse* (SFPP) Sterilizer factory-programmed sterilization cycles and cycle values

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
SFPP	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 6-3 for recommended quantities.*
SFPP	275°F (135°C)	3 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 6-3 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 6-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 6-3 for recommended quantities.*
SFPP	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 6-3 for recommended quantities.*
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 6-3 for recommended quantities.*
Liquid*	250°F (121°C)	45 minutes	N/A	*Refer to Table 6-4 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
DART Warm-Up	270°F (132°C)	3 minutes	1 minute	N/A
DART	270°F (132°C)	3 ½ minutes	1 minute	Bowie-Dick Test Pack, DART Test Pack
Leak Test	N/A	N/A	N/A	N/A

*The liquid cycle is for non-patient contact use only.

The following table lists STERIS's recommended loads by sterilizer size:

Table 6-3. Amsco Evolution Medium Steam Sterilizer recommended loads per sterilizer size

Sterilizer Size	Wrapped Instrument Trays	Fabric Packs
26" x 37 ½" x 42"	12	16
26" x 37 ½" x 54"	15	20

The following table is a guideline for liquid cycle processing:

Table 6-4. Amsco Evolution Medium Steam Sterilizer Liquid Cycle* Guideline

Number of Containers	Volume of Liquid In One Container	Minimum Recommended Sterilize Time at 250ºF (121ºC)
3	1000 ml	45 minutes

*The liquid cycle is for non-patient contact use only.

The Amsco Evolution Medium Steam Sterilizer is offered in the following chamber sizes:

- 26" x 26" x 49" (Model HC – 800)
- 26" x 26" x 61" (Model HC – 1000)

5. Discussion of Technology Comparison and Verification Activities

The Evolution Medium Sterilizers are the same as the predicate devices except for the specific modifications described in this submission. There are no differences in the indications for use or technology (including features, materials, and principles of operation) between the proposed and predicate devices. Therefore, the differences between the proposed and predicate devices are limited to the described modifications, and these proposed changes raise no new concerns of safety and effectiveness when compared to the predicate device.

The following table summarizes the verification activities that were performed with their respective acceptance criteria to ensure that these modifications do not affect the safety or effectiveness of the Evolution Medium Steam Sterilizers.

Device Modification	Verification / Validation Activity	Acceptance Criteria	Results of Verification /Validation
Control replacement	Performance testing Electrical safety	Per ST8 Per IEC 61010-1	Pass
Software modifications	Software validation	Software shall be appropriately verified and validated	Pass
Vacuum pump replacement	Performance testing	Per ST8	Pass
Printer replacement	Software validation	Software shall be appropriately verified and validated	Pass
Valve modifications	Performance testing	Per ST8	Pass
Switch modification	Actuation	Proper actuation, no alarms	Pass
Door mounting bracket modification	Door operation check	Proper function after multiple cycles	Pass

6. Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and perform at least as well as the legally marketed predicate device (K091731), Class II (21 CFR 880.6880), product code FLE.