



Food and Drug Administration  
10903 New Hampshire Avenue  
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March 9, 2018

STERIS Corporation  
Tony Piotrkowski  
Sr. Manager, Regulatory Affairs  
5960 Heisley Rd.  
Mentor, Ohio 44060

Re: K173481

Trade/Device Name: Amsco® Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)  
Regulation Number: 21 CFR 880.6880  
Regulation Name: Sterilizer, Ethylene Oxide Gas  
Regulatory Class: Class II  
Product Code: FLE  
Dated: December 12, 2017  
Received: January 11, 2018

Dear Mr. Tony 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

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

## Indications for Use

510(k) Number (if known)

**K173481**

Device Name

Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)

### Indications for Use (Describe)

The Amsco Evolution Medium Steam Sterilizer Models HC-900 and HC-1200 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

| 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. <i>Refer to Table 5-3 for recommended quantities.</i> |
| SFPP         | 275°F (135°C)         | 3 minutes      | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 5-3 for recommended quantities.</i>                  |
| Prevac       | 270°F (132°C)         | 4 minutes      | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 5-3 for recommended quantities.</i> |
| Gravity      | 250°F (121°C)         | 30 minutes     | 15 minutes | Fabric Packs. <i>Refer to Table 5-3 for recommended quantities.</i>                                                                           |
| 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. <i>Refer to Table 5-3 for recommended quantities.</i>                  |
| Gravity      | 270°F (132°C)         | 15 minutes     | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 5-3 for recommended quantities.</i>                  |
| Liquid*      | 250°F (121°C)         | 45 minutes     | N/A        | <i>Refer to Table 5-4 for recommended quantities.</i>                                                                                         |
| 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

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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<br>Trays | Fabric Packs |
|-------------------|-----------------------------|--------------|
| 26" x 37 ½" x 42" | 12                          | 18           |
| 26" x 37 ½" x 54" | 16                          | 30           |

The following table is a guideline for liquid cycle processing:

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

| Number of<br>Containers | Volume of Liquid In One<br>Container | Minimum Recommended<br>Sterilize Time at 250°F (121°C) |
|-------------------------|--------------------------------------|--------------------------------------------------------|
| 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 37½" x 42" (Model HC – 900)
- 26" x 37½" x 54" (Model HC – 1200)

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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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) Summary  
For  
Amsco Evolution Medium Steam Sterilizer**

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Submission Date: February 12, 2018

Premarket Notification Number: K173481

STERIS Corporation ■ 5960 Heisley Road ■ Mentor, OH 44060-1834 USA ■ 440-354-2600

**1. Device Name**

Trade Name: Amsco<sup>®</sup> Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)

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-900 and HC-1200), K091136.

**3. Description of Device**

The Amsco Evolution Medium Steam Sterilizer models HC-900 and HC-1200 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 37½" x 42" (Model HC – 900)
- 26" x 37½" x 54" (Model HC – 1200)

**4. Intended Use**

The Amsco Evolution Medium Steam Sterilizer Models HC-900 and HC-1200 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. <i>Refer to Table 6-3 for recommended quantities.</i> |
| Prevac       | 270°F (132°C)         | 4 minutes      | 5 minutes  | Single Fabric Pack                                                                                                                            |
| Gravity      | 250°F (121°C)         | 30 minutes     | 15 minutes | Fabric Packs. <i>Refer to Table 6-3 for recommended quantities.</i>                                                                           |
| Liquid*      | 250°F (121°C)         | 45 minutes     | N/A        | <i>Refer to Table 6-4 for recommended quantities.</i>                                                                                         |
| Prevac       | 275°F (135°C)         | 3 minutes      | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Gravity      | 270°F (132°C)         | 15 minutes     | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Gravity      | 250°F (121°C)         | 30 minutes     | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Gravity      | 270°F (132°C)         | 25 minutes     | 15 minutes | Fabric Packs. <i>Refer to Table 6-3 for recommended quantities.</i>                                                                           |
| 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. <i>Refer to Table 6-3 for recommended quantities.</i> |
| SFPP    | 275°F (135°C)         | 3 minutes      | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Prevac  | 270°F (132°C)         | 4 minutes      | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each and Fabric Packs. <i>Refer to Table 6-3 for recommended quantities.</i> |
| Gravity | 250°F (121°C)         | 30 minutes     | 15 minutes | Fabric Packs. <i>Refer to Table 6-3 for recommended quantities.</i>                                                                           |
| 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. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Gravity | 270°F (132°C)         | 15 minutes     | 30 minutes | Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. <i>Refer to Table 6-3 for recommended quantities.</i>                  |
| Liquid* | 250°F (121°C)         | 45 minutes     | N/A        | <i>Refer to Table 6-4 for recommended quantities.</i>                                                                                         |

**K173481 STERIS TRADITIONAL 510(k) PREMARKET NOTIFICATION**  
**Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)**

| 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                       | 18           |
| 26" x 37 ½" x 54" | 16                       | 30           |

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 250°F (121°C) |
|----------------------|-----------------------------------|-----------------------------------------------------|
| 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 37½" x 42" (Model HC – 900)
- 26" x 37½" x 54" (Model HC – 1200)

## **5. Description of Safety and Substantial Equivalence**

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.

| <b>Device Modification</b>         | <b>Verification / Validation Activity</b> | <b>Acceptance Criteria</b>                             | <b>Results of Verification /Validation</b> |
|------------------------------------|-------------------------------------------|--------------------------------------------------------|--------------------------------------------|
| Control replacement                | Performance testing<br>Electrical safety  | Per ST8<br>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 (K091136), Class II (21 CFR 880.6880), product code FLE.