



November 6, 2020

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

Re: K203061

Trade/Device Name: Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200),
Evolution Automated Loading and Unloading System (ALUS); Amsco Evolution
Medium Steam Sterilizer (Models HC-600 and HC-1500),
Evolution Automated Loading and Unloading System (ALUS); Amsco Evolution
Medium Steam Sterilizer (Models HC-800 and HC-1000),
Evolution Automated Loading and Unloading System (ALUS)

Regulation Number: 21 CFR 880.6880

Regulation Name: Steam Sterilizer

Regulatory Class: Class II

Product Code: FLE, PEC

Dated: October 7, 2020

Received: October 8, 2020

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 -S

For Kapil Panguluri, Ph.D.
Acting 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

510(k) Number (if known)

K2033061

Device Name

Amsco Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200),
Evolution Automated Loading and Unloading System (ALUS)

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

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 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 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)

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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Indications for Use

510(k) Number (if known)

K203061

Device Name

Amsco Evolution Medium Steam Sterilizer (Models HC-600 and HC-1500),
Evolution Automated Loading and Unloading System (ALUS)

Indications for Use (Describe)

The Amsco Evolution Medium Steam Sterilizer models HC-600 and HC-1500 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 4-4 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 | Model Number | Wrapped Instrument Trays | Fabric Packs |
|-------------------|--------------|--------------------------|--------------|
| 26" x 26" x 39" | HC-600 | 9 | 12 |
| 26" x 37 ½" x 60" | HC-1500 | 20 | 36 |

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 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 26" x 39" (660 mm x 660 mm x 991 mm), Model HC-600
- 26" x 37½" x 60" (660mm x 950mm x 1524mm), Model HC-1500

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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Indications for Use

510(k) Number (if known)

K203061

Device Name

Amsco Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000),
Evolution Automated Loading and Unloading System (ALUS)

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 250°F (121°C) |
|----------------------|-----------------------------------|---|
| 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)

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STERIS®



**510(k) Summary
For
Amsco Evolution Medium Steam Sterilizer
(Models HC-900 and HC-1200)
Evolution Automated Loading and
Unloading System (ALUS)**

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Submission Date: October 7, 2020

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

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

1. Device Name

Trade Name: Amsco® Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200)
Evolution Automated Loading and Unloading System (ALUS)

Device Class: Class II

Common/usual Name: Steam Sterilizer

Classification Name: Sterilizer, Steam

Classification Number: 21 CFR 880.6880

Product Code: FLE, PEC

2. Predicate Device

AMSCO Evolution Medium Steam Sterilizer (Models HC-900 and HC-1200), K173481.

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)

The Automated Load/Unload System (ALUS) automatically feeds loading cars packed with goods into and/or out of the sterilizer chamber, reducing the amount of handling by central supply workers. This includes ALUS tables for use with AMSCO Evolution medium steam sterilizers having automated chamber doors and the following chamber dimensions (width and height):

- 26 x 26" (660 x 660 mm)
- 26 x 37½" (660 x 953 mm)

4. Intended Use/Indications for 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:

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

- *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. 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):

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

Table 6-2. 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> |
| 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.

Table 6-3. 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 |

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

The following table is a guideline for liquid cycle processing:

Table 6-4. 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)

The Evolution Automated Loading and Unloading System (ALUS) is used for automated loading and unloading the Evolution Medium Steam Sterilizers.

5. Summary of Design and Verification Activities

No changes have been made to the sterilizer for addition of the ALUS system. All software to allow loading and cycle initiation was present in the predicate device including functionality to read the barcode and initiate the cycle.

The modification is inclusion of the hardware: conveyors, loading cars and barcode reader.

| Device Modification | Verification / Validation Activity | Acceptance Criteria | Verification / Validation Results |
|---------------------------|-------------------------------------|--|-----------------------------------|
| Addition of ALUS hardware | Functional testing | Automatic loading and unloading and initiation of the proper cycle | Pass |
| | UL 73: 2011 Ed.10 (2018) evaluation | Meet requirements for ETL certification | Pass |

The AMSCO Evolution Medium Steam Sterilizer with Automated Loading and Unloading System has met the established performance criteria.

6. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K173481), Class II (21 CFR 880.6880), product code FLE.



510(k) Summary
For
Amsco Evolution Medium Steam Sterilizer
(Models HC-600 and HC-1500)
Evolution Automated Loading and
Unloading System (ALUS)

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Submission Date: October 7, 2020

7. Device Name

Trade Name: Amsco® Evolution Medium Steam Sterilizer (Models HC-600 and HC-1500)
Evolution Automated Loading and Unloading System (ALUS)

Device Class: Class II

Common/usual Name: Steam Sterilizer

Classification Name: Sterilizer, Steam

Classification Number: 21 CFR 880.6880

Product Code: FLE, PEC

8. Predicate Device

AMSCO Evolution Medium Steam Sterilizer (Models HC-600 and HC-1500), K173485.

9. Description of Device

The Amsco Evolution Medium Steam Sterilizer models HC-600 and HC-1500 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 39" (Model HC – 600)
- 26" x 37 ½" x 66" (Model HC – 1500)

The Automated Load/Unload System (ALUS) automatically feeds loading cars packed with goods into and/or out of the sterilizer chamber, reducing the amount of handling by central supply workers. This includes ALUS tables for use with AMSCO Evolution medium steam sterilizers having automated chamber doors and the following chamber dimensions (width and height):

- 26 x 26" (660 x 660 mm)
- 26 x 37-1/2" (660 x 953 mm)

10. Intended Use/Indications for Use

The Amsco Evolution Medium Steam Sterilizer Models HC-600 and HC-1500 are designed for sterilization of heat and moisture-stable materials used in healthcare facilities and are available in two configurations:

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

- *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 6-5):

Table 6-5. 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 6-7 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 6-7 for recommended quantities.</i> |
| Liquid* | 250°F (121°C) | 45 minutes | N/A | <i>Refer to Table 6-8 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 6-7 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 6-7 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 6-7 for recommended quantities.</i> |
| Gravity | 270°F (132°C) | 25 minutes | 15 minutes | Fabric Packs. <i>Refer to Table 6-7 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 6-6):

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

Table 6-6. 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 6-7 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 6-7 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 6-7 for recommended quantities.</i> |
| Gravity | 250°F (121°C) | 30 minutes | 15 minutes | Fabric Packs. <i>Refer to Table 6-7 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 6-7 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 6-7 for recommended quantities.</i> |
| Liquid* | 250°F (121°C) | 45 minutes | N/A | <i>Refer to Table 6-8 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.

Table 6-7. Evolution Medium Steam Sterilizer recommended loads per sterilizer size

| Sterilizer Size | Model Number | Wrapped Instrument Trays | Fabric Packs |
|-------------------|--------------|--------------------------|--------------|
| 26" x 26" x 39" | HC-600 | 9 | 12 |
| 26" x 37 ½" x 66" | HC-1500 | 20 | 36 |

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

The following table is a guideline for liquid cycle processing:

Table 6-8. 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 Evolution Automated Loading and Unloading System (ALUS) is used for automated loading and unloading the Evolution Medium Steam Sterilizers.

11. Summary of Design and Verification Activities

No changes have been made to the sterilizer for addition of the ALUS system. All software to allow loading and cycle initiation was present in the predicate device including functionality to read the barcode and initiate the cycle.

The modification is inclusion of the hardware: conveyors, loading cars and barcode reader.

| Device Modification | Verification / Validation Activity | Acceptance Criteria | Verification / Validation Results |
|---------------------------|-------------------------------------|--|-----------------------------------|
| Addition of ALUS hardware | Functional testing | Automatic loading and unloading and initiation of the proper cycle | Pass |
| | UL 73: 2011 Ed.10 (2018) evaluation | Meet requirements for ETL certification | Pass |

The AMSCO Evolution Medium Steam Sterilizer with Automated Loading and Unloading System has met the established performance criteria.

12. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K173485), Class II (21 CFR 880.6880), product code FLE.



**510(k) Summary
For
Amsco Evolution Medium Steam Sterilizer
(Models HC-800 and HC-1000)
Evolution Automated Loading and
Unloading System (ALUS)**

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Submission Date: October 7, 2020

13. Device Name

Trade Name: Amsco® Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000)
Evolution Automated Loading and Unloading System (ALUS)

Device Class: Class II

Common/usual Name: Steam Sterilizer

Classification Name: Sterilizer, Steam

Classification Number: 21 CFR 880.6880

Product Code: FLE, PEC

14. Predicate Device

AMSCO Evolution Medium Steam Sterilizer (Models HC-800 and HC-1000), K173490.

15. 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 49" (Model HC – 800)
- 26" x 26" x 61" (Model HC – 1000)

The Automated Load/Unload System (ALUS) automatically feeds loading cars packed with goods into and/or out of the sterilizer chamber, reducing the amount of handling by central supply workers. This includes ALUS tables for use with AMSCO Evolution medium steam sterilizers having automated chamber doors and the following chamber dimensions (width and height):

- 26 x 26" (660 x 660 mm)
- 26 x 37-1/2" (660 x 953 mm)

16. Intended Use/Indications for 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:

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

- *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 6-9. 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 6-11 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 6-11 for recommended quantities.</i> |
| Liquid* | 250°F (121°C) | 45 minutes | N/A | <i>Refer to Table 6-12 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 6-11 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 6-11 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 6-11 for recommended quantities.</i> |
| Gravity | 270°F (132°C) | 25 minutes | 15 minutes | Fabric Packs. <i>Refer to Table 6-11 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):

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

Table 6-10. 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 6-11 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 6-11 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 6-11 for recommended quantities.</i> |
| Gravity | 250°F (121°C) | 30 minutes | 15 minutes | Fabric Packs. <i>Refer to Table 6-11 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 6-11 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 6-11 for recommended quantities.</i> |
| Liquid* | 250°F (121°C) | 45 minutes | N/A | <i>Refer to Table 6-12 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.

Table 6-11. 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 |

STERIS SPECIAL 510(k) PREMARKET NOTIFICATION
Modification of Amsco Evolution Medium Steam Sterilizer

The following table is a guideline for liquid cycle processing:

Table 6-12. 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 26” x 49” (Model HC – 800)
- 26” x 26” x 61” (Model HC – 1000)

The Evolution Automated Loading and Unloading System (ALUS) is used for automated loading and unloading the Evolution Medium Steam Sterilizers.

17. Summary of Design and Verification Activities

No changes have been made to the sterilizer for addition of the ALUS system. All software to allow loading and cycle initiation was present in the predicate device including functionality to read the barcode and initiate the cycle.

The modification is inclusion of the hardware: conveyors, loading cars and barcode reader.

| Device Modification | Verification / Validation Activity | Acceptance Criteria | Verification / Validation Results |
|---------------------------|-------------------------------------|--|-----------------------------------|
| Addition of ALUS hardware | Functional testing | Automatic loading and unloading and initiation of the proper cycle | Pass |
| | UL 73: 2011 Ed.10 (2018) evaluation | Meet requirements for ETL certification | Pass |

The AMSCO Evolution Medium Steam Sterilizer with Automated Loading and Unloading System has met the established performance criteria.

18. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device (K173490), Class II (21 CFR 880.6880), product code FLE.