K091731

SEP 17 2009

STERIS®

510(k) Summary
For
Amsco Evolution Medium Steam Sterilizer
Models HC-800 and HC-1000

STERIS Corporation
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Contact: Robert F. Sullivan
Senior Director
FDA Regulatory Affairs
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Summary Date: June 10, 2009

1. Device Name

Trade Name:	Amsco Evolution Medium Steam Sterilizer
Models:	HC-800 and HC-1200
Common/Usual Name:	Steam Sterilizer
Classification Name:	Steam Sterilizer (21 CFR 880.6880) Product Code 80 FLE

2. Predicate Device

K082435, Amsco Evolution Medium Steam Sterilizer, product code [FLE] cleared December 30, 2008.

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 49" (Model HC – 800)
- 26" x 26" x 61" (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 4-1):

Table 4-1. 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 4-3 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 4-3 for recommended quantities.*
Liquid	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 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 4-3 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 4-3 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 4-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 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 4-2):

Table 4-2. 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 4-3 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 4-3 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 4-3 for recommended quantities.*
Gravity	250°F (121°C)	30 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 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 4-3 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 4-3 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
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 4-3. 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 4-4. 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)

5. Description of Safety and Substantial Equivalence

A summary of the technological characteristics of the device subject of this premarket notification in comparison to those of the predicate devices is included in Table 5-5.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 17 2009

Mr. Robert F. Sullivan
Senior Director of FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road
Mentor, Ohio 44060-1834

Re: K091731
Trade/Device Name: Amsco Evolution Medium Steam Sterilizer
Regulation Number: 21 CFR 880. 6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FLE
Dated: August 13, 2009
Received: August 14, 2009

Dear Mr. Sullivan:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony O. Watson for
Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

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

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:

- *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 4-1):

Table 4-1. 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 4-3 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 4-3 for recommended quantities.*
Liquid	250°F (121°C)	45 minutes	N/A	*Refer to Table 4-4 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 4-3 for recommended quantities.*

Cycles	Sterilize Temperature	Sterilize Time	Dry Time	Recommended Load
Gravity	270°F (132°C)	15 minutes	30 minutes	Double wrapped instrument trays, maximum weight 25 lbs (11.3 kg) each. *Refer to Table 4-3 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 4-3 for recommended quantities.*
Gravity	270°F (132°C)	25 minutes	15 minutes	Fabric Packs. *Refer to Table 4-3 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 4-2):

Table 4-2. 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 4-3 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 4-3 for recommended quantities.*

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 4-3 for recommended quantities.*
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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 4-3 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 4-3 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 4-3. 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 4-4. 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)

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K091731

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091731