STERIS®

DEC 30 2008

510(k) Summary
For
Amsco Evolution Medium Steam Sterilizer

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Summary Date: December 29, 2008

1. Device Name

Trade Name:	Amsco Evolution Medium Steam Sterilizer
Common/usual Name:	Amsco Evolution Medium Steam Sterilizer
Classification Name:	Steam Sterilizer (21 CFR 880.6880, Product Code FLE.

2. Predicate Devices

- K010865, Amsco Century Medium Steam Sterilizer, product code [FLE] cleared May 31, 2001.
- K020747 Amsco Century Medium Steam Sterilizer, product code [FLE] cleared May 17, 2002.

3. Description of Device

The Amsco Evolution Medium Steam Sterilizer is designed for sterilization of heat and moisture-stabile 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 Steam Sterilizer is offered in the following chamber sizes:

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

4. Intended Use

The Amsco Evolution Medium Steam Sterilizer models HC-600 and HC-1500 are designed for sterilization of heat and moisture-stabile 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. 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. 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. 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 (Table 5-3) lists STERIS's recommended loads by sterilizer size:

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

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 (Table 5-4) provides a guideline for liquid cycle processing. The liquid cycle is for non-patient contact use only.

Table 5-4. Amsco Evolution Medium Steam Sterilizer liquid cycle processing 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:

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

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.

Table 5-5. Summary of the Proposed and Predicate Devices Technological Characteristics

General Sterilizer Features	**Amsco Evolution Medium Steam Sterilizer (subject of this Abbreviated 510(k) submission)**	**Amsco Century Medium Steam Sterilizer 26" x 26" (K020747, cleared 05/17/02)**	**Amsco Century Medium Steam Sterilizer (K010865, cleared 5/31/01)**
Intended Use	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stabile materials in healthcare facilities.	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stabile materials in healthcare facilities.	A steam sterilizer intended for sterilization of non-porous and porous, heat- and moisture-stabile materials in healthcare facilities.
Operating Principle	Steam is the sterilizing agent.	Steam is the sterilizing agent.	Steam is the sterilizing agent.
Sterilization Cycles Offered	Prevac Gravity SFPP Liquid	Prevac Gravity Wrap/SFPP SFPP Liquid	Prevac Gravity Wrap/SFPP SFPP Liquid
Chamber Sizes	26" x 26" x 39" 26" x 37.5" x 60"	26" x 26" x 39" 26" x 26" x 49" 26" x 26" x 61"	26" x 37.5" x 36" 26" x 37.5" x 48" 26" x 37.5" x 60"
Chamber Door	Type 316L stainless steel Vertical Sliding (26"x26") Hinged or Horizontal Sliding (26"x37½")	Type 316L stainless steel Vertical Sliding only	Type 316L stainless steel Hinged or Horizontal Sliding
Shell Assembly	Type 316L stainless steel ASME certified	Type 316L stainless steel ASME certified	Type 316L stainless steel ASME certified
Control Technology	Unity Controller Touch Screen 8.4" Display Ink on Paper Printer	Century Controller Touch Screen Vacuum Fluorescent Display Ink on Paper Printer	Century Controller Touch Screen Vacuum Fluorescent Display Ink on Paper Printer
Process Monitors	Chamber Transducer Dual Element Chamber Drain Sensor	Chamber Transducer Chamber Drain Sensor	Chamber Transducer Chamber Drain Sensor
Safety Devices	Pressure Relief Valve Chamber Float Switch Control Lockout Switch	Pressure Relief Valve Chamber Float Switch Control Lockout Switch	Pressure Relief Valve Chamber Float Switch Control Lockout Switch

Effectiveness

Effectiveness of sterilizer function and exposure time recommendations was demonstrated by complete kill of biological indicators and by verifying an appropriate safety factor or sterility assurance level (SAL) of at least 10^{-6} probability of survival. STERIS validates its sterilization cycles using recommended practices, standards and guidelines developed by independent organizations such as the Association for the Advancement of Medical

Instrumentation (AAMI). The Amsco Evolution Steam Sterilizer was validated to meet the requirements of ANSI/AAMI ST8, Fourth Edition, November 2001.

The results of the Amsco Evolution Steam Sterilizer validation studies demonstrate that the sterilizer performs as intended. The results are summarized as follows:

- Empty chamber testing performed as described in Section 5.4.2.5 of ANSI/AAMI-ST8, for the Prevac, Gravity, Liquid and SFPP cycles. These cycles demonstrated that the sterilizer is capable of providing steady state thermal conditions within the chamber that are consistent with the predicted sterility assurance level (SAL) in the load. The sterilizer meets the requirements of Sections 4.4.2.2 and 4.4.2.5 of ANSI/AAMI-ST8.
- All SFPP cycles validated using the fabric test pack, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All SFPP cycles validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All GRAVITY cycles validated using the fabric test pack, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and no evidence of wet spots.
- All GRAVITY cycles validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle cycle analysis, moisture retention of less than 20% increase in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.
- All PREVAC cycles validated using the fabric test pack, described in Section 5.5.2.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.2 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, moisture retention of less than 3% increase in presterilization test pack weight, and exhibited no wet spots.
- All PREVAC cycles validated using full load instrument trays, described in 5.5.4.1 of ANSI/AAMI-ST8, were qualified according to Section 5.5.4 ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} using half-cycle analysis, moisture retention of less than 20% increase

in presterilization weight of the towel, and no evidence of wet spots on the outer wrapper.

- All LIQUID cycles validated using three 1,000 ml flasks, described in Section 5.5.3.1 of the ANSI/AAMI-ST8, were qualified according to Section 5.5.3 of ANSI/AAMI-ST8. These cycles demonstrated a sterility assurance level of at least 10^{-6} through achievement of a time-at-temperature sufficient to produce an F_0 value of at least 12, water loss not exceeding 50 ml, and automatic sealing of the flask closure.
- The DART cycle validated using the Bowie-Dick Test Pack, as described in 5.6.1.1 of the ANSI/AAMI-ST8, was qualified according to Section 5.6.1 of the ANSI/AAMI-ST8, and demonstrated a uniform color change throughout the test sheet.
- The software validation for the cycle operation was performed according to FDA's moderate level of concern recommendations provided in the document *"Guidance for the Content for Premarket Submissions for Software Contained in Medical Devices (05/11/05)."*

Safety

STERIS sterilizers including the Amsco Evolution Steam Sterilizer have been designed, constructed and tested to meet the safety and performance requirements of various national safety codes and standards. The Amsco Evolution Steam Sterilizer complies with the following requirements:

- Underwriters Laboratory (UL) Electrical Safety Code 61010-1 certified by Intertek Testing Services (ITS).
- Canadian Standards Association (CSA) Standard C22.2 No. 1010-1 as certified by Intertek Testing Services.
- American Society of Mechanical Engineers (ASME), Section VIII, Division 1 for unfired pressure vessels.

Hazards – Failure of Performance

Failure of the sterilization process can lead to incidence of cross contamination, the transmission of potentially infectious organisms from one infected person to another who was not otherwise infected prior to the incident.

To avoid failure, the user must ensure that the materials, instruments and devices to be sterilized are thoroughly cleaned, the manufacturer's instructions for use are followed, the cycle to be used for each type of sterilizer load has been validated, the sterilizer has been maintained in accordance with the sterilizer manufacturer's recommended maintenance schedule and is operating properly, and each sterilizer load is monitored with available and validated biological and chemical sterilization process indicators.

Today, there are many steam sterilizers in daily use in hospitals throughout the United States. The incidence of sterilizer malfunction or sterilization process failure is relatively rare. Further, there are no known reports in the literature of

patient infections that have resulted from steam sterilizer failures. The technology designed into STERIS steam sterilizers including the Amsco Evolution Steam Sterilizer provide PC Controller safeguards that abort the cycle and give appropriate signals, alerts and warnings when required conditions have not been met or when a malfunction occurs.

User Information

STERIS conducts in-house training and has developed a series of user training videos that provide helpful information about the appropriate use of steam sterilizers. STERIS further provides information to the user that is intended to ensure safe and effective use of steam sterilization in its detailed Operator Manual and other labeling. STERIS also recommends the use and periodic review of the AAMI steam sterilization standards to ensure further assurance of the safe and effective use of steam sterilization equipment in healthcare facilities.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 2008

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

Re: K082435
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: December 08, 2008
Received: December 09, 2008

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Chiu S. Lin, Ph. D
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): K082435

Device Name: Amsco Evolution Medium Steam Sterilizer

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:

- *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 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.*
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 following table (Table 4-3) 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 39"	9	12
26" x 37 ½" x 60"	20	36

The following table (Table 4-4) 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 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

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)

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

510(k) Number: K 082435

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