K093493

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Sterilcontainer S for
STERRAD 200, STERRAD NX, and STERRAD NX100
July 27, 2010

JUL 27 2010

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Kathy A. Racosky 610-984-9291 (phone) 610-791-6882 (fax)

TRADE NAME:	Aesculap Sterilcontainer S
COMMON NAME:	Sterilization Container Wrap
CLASSIFICATION NAME:	Wrap, Sterilization
REGULATION NUMBER:	880.6850
PRODUCT CODE:	FRG

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the SterilContainer S is substantially equivalent to:

- Aesculap STERRAD 100S Compatible Sterilcontainer (K040865).
- SteriTite Universal Container System with MediTray Products for STERRAD 200, STERRAD NX, Ozone 125L, Sterilization, and Prevacuum Steam Flash Sterilization (K080558).

DEVICE DESCRIPTION

The Aesculap Sterilcontainer S is designed as a container system that will allow for sterilization and storage of other medical devices. This container is designed to be compatible for use with the STERRAD sterilization processes [200, NX (Standard cycle and Advanced cycle), and 100NX (Standard cycle and Flex cycle]. The container is made from non-anodized Aluminum and utilizes a disposable (single use) polypropylene filter. The Sterilcontainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

INDICATIONS FOR USE:

The Aesculap Sterilcontainer S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and disposable polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container has been validated with stainless steel lumens, hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the STERRAD 200, STERRAD NX (Standard cycle and Advanced cycle), and STERRAD 100NX (Standard cycle and Flex cycle). The Sterilcontainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

The Sterilcontainer S is recommended for surface and lumens:

STERRAD 200, stainless steel lumens ≥ 3mm I.D. x ≤ 400mm L
STERRAD NX standard cycle, stainless steel lumens ≥ 2mm I.D. x ≤ 400mm L
STERRAD NX advanced cycle, stainless steel lumens ≥ 1mm I.D. x ≤ 500mm L
STERRAD 100NX standard cycle, stainless steel lumens ≥ 0.7mm I.D. x ≤ 500mm L
STERRAD 100NX flex cycle, porous lumens (flexible endoscope) ≥ 1mm I.D. x ≤ 850mm L

30 days of shelf life testing has been conducted for the Sterilicontainer S.

The attached tables identify which products may be sterilized in which STERRAD sterilization cycle.

TABLE 1
SterilContainer S Compatible Containers in STERRAD 200

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46
JM442	Full Size Perforated Bottom 135mm (6")	21.46
JM444	Full Size Perforated Bottom 187mm (8")	21.46
JM740	¾ Size Perforated Bottom 90mm(4 ¼")	14.42
JM741	¾ Size Perforated Bottom 120mm (5 ½")	14.42
JM742	¾ Size Perforated Bottom 135mm (6")	14.42
JM340	½ Size Perforated Bottom 90mm (4 ¼")	14.42
JM341	½ Size Perforated Bottom 120mm (5 ½")	14.42
JM342	½ Size Perforated Bottom 135mm (6")	14.42
JM344	½ Size Perforated Bottom 187mm (8")	14.42
JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	14.42
JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	14.42
JM021	Extra Long Mini Bottom 73mm (3")	7.64
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	
See JM094 & JM096	¼ Size Lid	
JM020	Extra Long Mini Lid	

Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 2
SterilContainer S Compatible Containers in STERRAD NX Standard and Advanced Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46
JM740	¾ Size Perforated Bottom 90mm (4 ¼")	13.85
JM741	¾ Size Perforated Bottom 120mm (5 ½")	13.85
JM742	¾ Size Perforated Bottom 135mm (6")	13.85
JM340	½ Size Perforated Bottom 90mm (4 ¼")	13.85
JM341	½ Size Perforated Bottom 120mm (5 ½")	13.85
JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	13.85
JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	13.85
JM021	Extra Long Mini Bottom 73mm (3")	7.64
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	
See JM094 & JM096	¼ Size Lid	
JM020	Extra Long Mini Lid	

Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 3
SterilContainer S Compatible Containers in STERRAD 100NX Standard Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46
JM442	Full Size Perforated Bottom 135mm (6")	21.46
JM444	Full Size Perforated Bottom 187mm (8")	21.46
JM740	¾ Size Perforated Bottom 90mm(4 ¼")	13.85
JM741	¾ Size Perforated Bottom 120mm (5 ½")	13.85
JM742	¾ Size Perforated Bottom 135mm (6")	13.85
JM340	½ Size Perforated Bottom 90mm (4 ¼")	13.85
JM341	½ Size Perforated Bottom 120mm (5 ½")	13.85
JM342	½ Size Perforated Bottom 135mm (6")	13.85
JM344	½ Size Perforated Bottom 187mm (8")	13.85
JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	13.85
JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	13.85
JM021	Extra Long Mini Bottom 73mm (3")	7.64
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	
See JM094 & JM096	¼ Size Lid	
JM020	Extra Long Mini Lid	

Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 4
SterilContainer S Compatible Containers in STERRAD 100NX Flex Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	9.67
JM441	Full Size Perforated Bottom 120mm (5 ½")	9.67
JM442	Full Size Perforated Bottom 135mm (6")	9.67
JM444	Full Size Perforated Bottom 187mm (8")	9.67
JM740	¾ Size Perforated Bottom 90mm(4 ¼")	9.67
JM741	¾ Size Perforated Bottom 120mm (5 ½")	9.67
JM742	¾ Size Perforated Bottom 135mm (6")	9.67
JM340	½ Size Perforated Bottom 90mm (4 ¼")	9.67
JM341	½ Size Perforated Bottom 120mm (5 ½")	9.67
JM342	½ Size Perforated Bottom 135mm (6")	9.67
JM344	½ Size Perforated Bottom 187mm (8")	9.67
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	

Note: Full, ¾, and ½ size containers have been validated with 1 PTFE/PE lumen per container system.

TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

The Aesculap Sterilcontainer S is compatible for use in STERRAD 200, STERRAD NX (Standard cycle and Advanced cycle), and STERRAD 100NX (Standard cycle and Flex cycle). The Sterilcontainer is offered in similar shapes and sizes as the predicate devices. The material used for the STERRAD Compatible Aesculap Sterilcontainer S is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications 510(k)'s" for Aesculap Sterilcontainer S was completed. The Aesculap Sterilcontainer S was fully validated for STERRAD 200, STERRAD NX (Standard cycle and Advanced cycle), and STERRAD 100NX (Standard cycle and Flex cycle).Sterilization Systems. This validation was conducted in accordance with FDA guidance and available AAMI standards by a qualified testing laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Kathy Racosky
Regulatory Affairs Specialist
AESCULAP, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUL 27 2010

Re: K093493
Trade/Device Name: AESCULAP Sterilcontainer S
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 29, 2010
Received: June 30, 2010

Dear Ms. Racosky:

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.

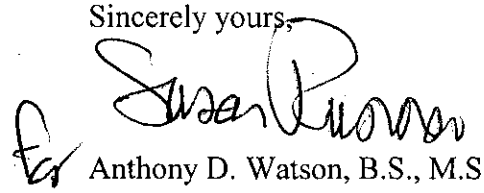
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/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 Small Manufacturers, International and Consumer Assistance 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 yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
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 STATEMENT

JUL 27 2010

K093493

510(k) Number:_____

Device Name: ***Aesculap Sterilcontainer S***

Indications for Use:

The Aesculap Sterilcontainer S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and disposable polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container has been validated with stainless steel lumens, hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the STERRAD 200, STERRAD NX (Standard cycle and Advanced cycle), and STERRAD 100NX (Standard cycle and Flex cycle). The Sterilcontainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

The Sterilcontainer S is recommended for surface and lumens:

STERRAD 200, stainless steel lumens ≥ 3mm I.D. x ≤ 400mm L
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STERRAD 100NX standard cycle, stainless steel lumens ≥ 0.7mm I.D. x ≤ 500mm L
STERRAD 100NX flex cycle, porous lumens (flexible endoscope) ≥ 1mm I.D. x ≤ 850mm L

30 days of shelf life testing has been conducted for the Sterilicontainer S.

The attached tables identify which products may be sterilized in which STERRAD sterilization cycle.

Prescription Use_____ and/or Over-the-Counter Use ___X_____

(per 21 CFR 801 Subpart D) (per 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: K093493

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Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 2
SterilContainer S Compatible Containers in STERRAD NX Standard and Advanced Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
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TABLE 3
SterilContainer S Compatible Containers in STERRAD 100NX Standard Cycle

Item #	Description	Total loaded container weight (lbs)
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Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 4
SterilContainer S Compatible Containers in STERRAD 100NX Flex Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	9.67
JM441	Full Size Perforated Bottom 120mm (5 ½")	9.67
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Note: Full, ¾, and ½ size containers have been validated with 1 PTFE/PE lumen per container system.