K062510

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

Aesculap Sterilcontainer System (Ozone Indication)
24 October 2006

NOV 17 2006

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
CONTACT:	Matthew M. Hull 610-984-9072 (phone) 610-791-6882 (fax)
TRADE NAME:	Aesculap Sterilcontainer System
COMMON NAME:	Sterilization Container
CLASSIFICATION NAME:	Wrap, Sterilization
REGULATION NUMBER:	880.6850
PRODUCT CODE:	FRG

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the *Sterilcontainer System for Ozone Sterilization* is substantially equivalent to:

Aesculap Sterilcontainer System (K792558) & (K053389)

DEVICE DESCRIPTION

The Aesculap Sterilcontainer 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 ozone sterilization. The container is made from anodized aluminum and utilizes a disposable (single use) paper filter.

INDICATIONS FOR USE

The Aesculap Sterilcontainer System is intended to be used to enclose another medical device(s) that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed device(s) until used. The Aesculap Sterilcontainer System has been validated for use in ozone sterilization systems (TSO3 125L) to include hinged devices and lumened devices as small as 3mm (diameter) and 550 mm (length).

TECHNOLIGICAL CHARACTERISTICS(compared to predicate(s))

This is exactly the same Aesculap sterilization container system that was cleared for use in prevacuum and gravity steam in 510(k) # K792558 and for use in flash sterilization in 510(k) #K053389. The anodized aluminum Aesculap Sterilcontainer was used by TSO3 in the validation of their 125L ozone sterilizer which was cleared in 510(k) #K020875. The version of the Aesculap container that is the subject of this submission is the same except for minor modifications to enhance the containers long-term compatibility with ozone sterilizer processing.

PERFORMANCE DATA

The modified Aesculap Sterilcontainer system was fully validated for the additional indication of ozone sterilization by TSO3 in their model 125L sterilizer. This validation was conducted in accordance with FDA guidance and available AAMI standards by qualified testing laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2006

Mr. Matthew M. Hull
Regulatory Affairs Manager
Aesculap®, Incorporated
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K062510
Trade/Device Name: Aesculap Sterilcontainer System
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: October 24, 2006
Received: October 25, 2006

Dear Mr. Hull:

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.

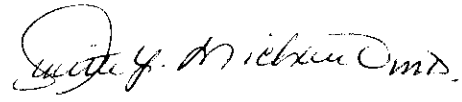
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K062510

Device Name: ***Aesculap Sterilcontainer System***

Indications for Use:

The Aesculap Sterilcontainer System is intended to be used to enclose another medical device(s) that are to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed device(s) until used. The Aesculap Sterilcontainer System has been validated for use in an ozone sterilization system (TSO3 125L) to include hinged devices and lumened devices as small as 3mm (diameter) and 550 mm (length).

The following validated parameters are based on the validation of the Aesculap® Sterilcontainer in an ozone sterilization cycle using a TSO_3 125L Sterilizer.

Phase	Typical values	Actual values
1 – Vacuum	Pressure: approx. 1 torr	1 torr
2 – Humidification	Pressure range: 31-44 torr	34-35 torr
3 – Injection	Ozone concentration range: 160 – 200 mg/L Pressure range: 400-500 torr Ozone dose injected: 85 mg/L	170-173 mg/L 457-460 torr 85 mg/L
4 – Exposure	Pressure range: 400-500 torr Duration: approx. 15 minutes	458-461 torr 15 minutes
5 – Vacuum	Pressure: approx. 1 torr	1 torr
6 – Humidification	Pressure range: 31-44 torr	34-37 torr
7 – Injection	Ozone concentration range: 160 – 200 mg/L Pressure range: 400-500 torr Ozone dose injected: 85 mg/L	170-177 mg/L 458-462 torr 85 mg/L
8 – Exposure	Pressure range: 400-500 torr Duration: approx. 15 minutes	459-462 torr 15 minutes
9 – Ventilation		21 minutes

The following containers and accessories are included in this system:

Item Description

FULL-SIZE LID W/RETENTION PLATE RED
FULL-SIZE LID W/RETENTION PLATE BLUE
FULL-SIZE LID W/RETENTION PLATE GREEN
FULL-SIZE LID W/RETENTION PLATE GOLD
FULL-SIZE LID W/RETENTION PLATE SILVER
FULL-SIZE SOLID BOTTOM 90MM
FULL-SIZE SOLID BOTTOM120MM
FULL-SIZE SOLID BOTTOM135MM
FULL-SIZE SOLID BOTTOM 187MM
FULL-SIZE SOLID BOTTOM 247MM
FULL-SIZE PERF BOTTOM90MM
FULL-SIZE PERF BOTTOM 120MM
FULL-SIZE PERF BOTTOM 135MM
FULL-SIZE PERF BOTTOM 187MM
EXTRA LONG CONTAINER PERF BOTTOM 187MM

Sheila A. Murphey DDS

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

510(k) Number: K062510

FULL-SIZE PERF BOTTOM 247MM
1/1 SIZE PERF BASKET 485X253X76MM
1/1 SIZE PERF BASKET LID 489X257MM
1/1 SIZE PERF BASKET 540X253X36MM
1/1 SIZE PERF BASKET 540X253X56MM
1/1 SIZE PERF BASKET 540X253X76MM
1/1 SIZE PERF BASKET 540X253X106MM
1/1 SIZE PERF BASKET LID 544X257MM
FULL-SIZE WIRE BASKET 30MM
FULL-SIZE WIRE BASKET 50MM
FULL-SIZE WIRE BASKET 70MM
FULL-SIZE WIRE BASKET 100MM
FULL-SIZE INSTRUMENT PAD
SILICONE BASKET LINER FULL-SIZE
3/4-SIZE LID W/RETENTION PLATE RED
3/4-SIZE LID W/RETENTION PLATE BLUE
3/4-SIZE LID W/RETENTION PLATE GREEN
3/4-SIZE LID W/RETENTION PLATE GOLD
3/4-SIZE LID W/RETENTION PLATE SILVER
3/4-SIZE SOLID BOTTOM 90MM
3/4-SIZE SOLID BOTTOM 120MM
3/4-SIZE SOLID BOTTOM 135MM
3/4-SIZE PERF BOTTOM90MM
3/4-SIZE PERF BOTTOM 120MM
3/4-SIZE PERF BOTTOM 135MM
3/4 SIZE PERF BASKET 406X253X36MM
3/4 SIZE PERF BASKET 406X253X56MM
3/4 SIZE PERF BASKET 406X253X76MM
3/4 SIZE PERF BASKET 406X253X106MM
3/4 SIZE PERF BASKET LID 410X257MM
3/4-SIZE WIRE BASKET 25MM
3/4-SIZE WIRE BASKET 50MM
3/4-SIZE WIRE BASKET 70MM
3/4-SIZE WIRE BASKET 100MM
3/4-SIZE INSTRUMENT PAD
1/2-SIZE LID W/RETENTION PLATE RED
1/2-SIZE LID W/RETENTION PLATE BLUE
1/2-SIZE LID W/RETENTION PLATE GREEN
1/2-SIZE LID W/RETENTION PLATE GOLD
1/2-SIZE LID W/RETENTION PLATE SILVER
1/2-SIZE SOLID BOTTOM 90MM
1/2-SIZE SOLID BOTTOM120MM
1/2-SIZE SOLID BOTTOM 135MM
1/2-SIZE SOLID BOTTOM187MM
1/2-SIZE SOLID BOTTOM 247MM
1/2-SIZE PERF BOTTOM 90MM
1/2-SIZE PERF BOTTOM 120MM
1/2-SIZE PERF BOTTOM 135MM
1/2-SIZE PERF BOTTOM 187MM
1/2-SIZE PERF BOTTOM247MM
1/2-SIZE WIRE BASKET50MM
1/2-SIZE WIRE BASKET 30MM
1/2-SIZE WIRE BASKET 70MM

1/2-SIZE WIRE BASKET100MM
1/2 SIZE PERF BASKET 243X253X36MM
1/2 SIZE PERF BASKET 243X253X56MM
1/2 SIZE PERF BASKET 243X253X76MM
1/2 SIZE PERF BASKET 243X253X106MM
1/2 SIZE PERF BASKET LID 247X257MM
HALF-SIZE INSTRUMENT PAD
SILICONE BASKET LINER 1/2-SIZE
MINI-SIZE LID W/RETENTION PLATE RED
MINI-SIZE LID W/RETENTION PLATE BLUE
MINI-SIZE LID W/RETENTION PLATE GREEN
MINI-SIZE LID W/RETENTION PLATE GOLD
MINI-SIZE LID W/RETENTION PLATESILVER
MINI-SIZE SOLID BOTTOM 30MM
MINI-SIZE SOLID BOTTOM 57MM
MINI-SIZE PERF BOTTOM 40MM
MINI-SIZE PERF BOTTOM 38MM
MINI-SIZE PERF BOTTOM 67MM
MINI CONTAINER 310X140X67MM SILVER
MINI-HALF WIRE BASKET WITH LID
MICRO-INST BASKET W/LID 235X137X42MM
MINI-SIZE PERF BASKETW/LID49MM
MINI-SIZE INSTRUMENT PAD
SILICONE PAD BLUE 470X230X30MM
SILICONE MAT LONG F/MD375 JF232R
SILICONE PAD 277X126X17
SILICONE PAD 250X239X17
ROUND PAPER FILTERS
STRINGER OPEN 350X65MM
STRINGER OPEN 150X65MM
STRINGER OPEN 150X125MM
STRINGER OPEN 200X125MM
STRINGER CLOSED W/LOCK 100X65MM
STRINGER CLOSED W/LOCK 150X125MM
STRINGER CLOSED W/LOCK 200 X 125MM
STRINGER CLOSED W/LOCK 300 X 125MM
STRINGER CLOSED W/LOCK 250 X 125MM
STRINGER CLOSED W/LOCK150 X 65MM

Prescription Use _____ and/or Over-the-Counter Use ____X____

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)