K102146

CONFIDENTIAL DOCUMENT

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510(k) Summary (as required by 21 CFR 807.92(c))

Manufacturer Name and Address

Bahadir USA Corp.
275 West Hoffman Avenue
Lindenhurst, NY 11757
Contact: Ismail Kilic
Tel: 631-608-8522

NOV 18 2010

Submitter / Contact Person / Regulatory Correspondent

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510(k) Written By: Joseph Azary / Orchid Design

Date Prepared

Revised September 23, 2010

Name of Device

BAHADIR STERILIZATION TRAYS

Classification Name

Sterilization Wraps, Trays, Containers
Class 2 – KCT

Predicate Device

Miltex Rigid Sterilization Trays – K050570
Sklar – SklarLite Rigid Sterilization Container – K091720

Description of the Device
Intended Use

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices using steam sterilizers. Sterilized devices may be stored and transferred in the container.

The devices included in this submission are to be used with a pre-vacuum cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes.

The devices (natural aluminum color containers and lids) subject to this submission are as follows:

Full Size 1/1 Y110.20
Full Size 1/1 Y110.15
Full Size 1/1 Y110.13
Full Size 1/1 Y110.10
¾ Size Y210.10
¾ Size Y210.15
¾ Size Y210.13
½ Size Y310.20
½ Size Y310.15
½ Size Y310.13
½ Size Y310.10

The maximum load weight is 24.75 lbs for full size, 12.5 lbs for ¾ size, and 9.25 lbs for ½ size. The sterilization validation included three types of loads, empty, full load of textiles, and full load of surgical instruments.

The subject trays are not validated for use with lumened devices, air driven instruments, power systems, or cannulized instruments.

DESCRIPTION

The devices included in this submission are to be used with a pre-vacuum cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes. Stacking during sterilization is not recommended.

The devices subject to this submission are as follows:

Full Size 1/1 Y110.20 (580 x 280 x 200mm)
Full Size 1/1 Y110.15 (580 x 280 x 150mm)
Full Size 1/1 Y110.13 (580 x 280 x 135mm)
Full Size 1/1 Y110.10 (580 x 280 x 100mm)
¾ Size Y210.15 (465 x 280 x 150mm)
¾ Size Y210.13 (465 x 280 x 135mm)
¾ Size Y210.10 (465 x 280 x 100mm)
½ Size Y310.20 (285 x 280 x 200mm)
½ Size Y310.15 (285 x 280 x 150mm)
½ Size Y310.13 (285 x 280 x 135mm)
½ Size Y310.10 (285 x 280 x 100mm)

The maximum load weight is 24.75 lbs for full size, 12.5 lbs for ¾ size, and 9.25 lbs for ½ size.

The devices are composed of anodized aluminum (this does not include colored anodized lids).

Comparison to Predicate Devices

The containers are the same design, same materials, same shapes, and sizes.

Feature	Bahadir	Miltex K072563	SklarLite K091720
Intended Use	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers for 270 F for 4 minutes with 20 minutes (minimum) dry time.	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices, including surfaces and lumens, using gravity steam sterilizers.	Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers for 270 F for 4 minutes with 30 minutes (minimum) dry time.
Material	Aluminum Alloy, stainless steel handles, silicone seal, paper filter	Aluminum Alloy, stainless steel handles, silicone seal, paper filter	Aluminum Alloy, stainless steel handles, silicone seal, paper filter
Filter	Paper Filter	Paper Filter PTFE Teflon Filter (for Ethylene Oxide) *Miltex had EO cleared in another 510k.	Paper Filter
Sterilization Method	Steam	Ethylene Oxide Steam *Miltex has EO cleared in another 510k	Steam
Configurations / Dimensions	Includes ½ size, ¾ size, and full size	Includes ½ size, ¾ size, and full size* *Miltex has their dimension in inches. The below is a conversion to metric	Full size 580mm x 280mm x 200mm 580mm x 280mm x 150mm 580mm x 280mm x

	Full size 580mm x 280mm x 200mm 580mm x 280mm x 150mm 580mm x 280mm x 135mm 580mm x 280mm x 100mm ¾ Size 465mm x 280mm x 150mm 465mm x 280mm x 135mm 465mm x 280mm x 100mm ½ size 285mm x 280mm x 200mm 285mm x 280mm x 150mm 285mm x 280mm x 135mm 285mm x 280mm x 100mm	units. Full size 580mm x 280mm x 150mm 580mm x 280mm x 135mm 580mm x 280mm x 100mm ¾ Size 465mm x 280mm x 150mm 465mm x 280mm x 135mm 465mm x 280mm x 100mm ½ size 285mm x 280mm x 150mm 285mm x 280mm x 135mm 285mm x 280mm x 100mm	135mm 580mm x 280mm x 100mm 580mm x 280mm x 260mm ¾ Size 465mm x 280mm x 150mm 465mm x 280mm x 135mm 465mm x 280mm x 100mm ½ size 285mm x 280mm x 200mm 285mm x 280mm x 150mm 285mm x 280mm x 135mm 285mm x 280mm x 100mm 285mm x 280mm x 260mm
Perforation	The units included in this submission include perforated lids and non-perforated bottoms.	The units included in their 510k included perforated lids and perforated bottoms.	The units included in their 510k included perforated and non-perforated lids and perforated and non-perforated bottoms.
Air Permeance	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.	Permits entry of sterilization agent and prevents microbial migration during storage.
Intended to be re-used	Yes	Yes	Yes
Sealed	Yes	Yes	Yes
Conformance to AAMI ST 77	Yes	Yes	Yes
Gasket	Silicone Based (gray color)	Silicone Based (red color)	Silicone Based (gray color)
Handles	Wider handles with silicone holder	Smaller handles (no holder)	Smaller handles (no holder)
Cycle Parameters	270 F at 4 minutes 20 minutes drying	270 F at 4 minutes 20 minutes drying	270 F at 4 minutes 30 minutes drying

The differences are as follows:

- Sterilization Method (Miltex has received FDA to also use Ethylene Oxide. Bahadir USA is not pursuing EO at this time).
- Filter (the devices are offered with paper filters, but Miltex also offers a PTFE Teflon filter for EO)
- The devices use a silicone based gasket around the lid. There is a difference in color. Bahadir USA and Sklar use gray and Miltex uses red. We believe this difference is more cosmetic than performance related.
- Both devices have stainless steel handles. The handles on the Bahadir USA containers are wider and include a silicone holder to prevent the user from getting burned when the handles are hot.
- The Bahadir USA containers in this submissions are with perforated lids and non-perforated bottoms. The Miltex and Sklar includes perforated lids and bottoms.
- The Sklar and Miltex 510(k)'s included larger range of sizes.
- Sklar is offered in anodized colored lids, whereas Bahadir and Miltex in silver (aluminum color).

Non-Clinical Tests Performed

The devices were subjected to cleaning validation, aging studies, half cycle, sterility testing and performance testing.

Summary

In conclusion we believe the devices are substantially equivalent to the predicate devices and do not introduce new issues of safety or effectiveness.

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

Mr. Ismail Kilic
President
Bahadir USA Corporation
275 West Hoffman Avenue
Lindenhurst, New York 11757

NOV 18 2010

Re: K102146
Trade/Device Name: Bahadir USA Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: November 1, 2010
Received: November 8, 2010

Dear Mr. Ismail:

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.

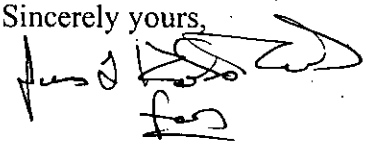
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

K102146

510(k) Number (if known):

Device Name: Bahadir USA Sterilization Trays

NOV 18 2010

Indications For Use:

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The subject trays are not validated for use with lumened devices, air driven instruments, power systems, or cannulized instruments.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 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: K102146