K050570

JUL 25 2005

Miltex
Redefining Excellence

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510(k) Summary [21 CFR §807.92]

Prepared: February 25, 2005

Device Trade Name: Miltex Rigid Sterilization Container System.

Device Common Name: Rigid Sterilization Container.

Classification Name: Sterilization wrap containers, trays, cassettes, and other accessories.

Class of Device: Class II device, product code KCT

Predicate Device: SteriTite® Rigid Sterilization Container System with MediTray Products- Case Medical, Incorporated- K023614

Official Contact: Lee Zagar, Vice President Quality Assurance and Regulatory Affairs

Device Description:
The Miltex Rigid Sterilization Container System consists of a family of rigid, re-usable, sealed containers that provides an effective sterilization packaging method for medical devices. Container bottoms and lids, within a given size, are interchangeable. The system is composed of the following components:

- Container bottoms (both perforated and non-perforated versions)
- Container baskets,
- Container lids (perforated only), and
- Container color-coding "labels."

The container system is designed for sterilant penetration through perforations in the lid and container bottom models that are perforated.

Intended Use:
The Miltex Rigid Sterilization Container System is intended for use in hospitals and health care 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 high vacuum steam sterilizers. The containers have been validated for sterilization of instruments with lumens up to 3 mm I.D. by 400 mm length, for the Full (large) size container and up to 3mm I.D. by 200mm length for the ½ (small) and ¾ (medium) size containers. Sterilized devices may be stored and transported within the container.

Technological Characteristics:

A comparison of the technology characteristics of the Miltex Rigid Sterilization Containers to the predicate device's.

Properties	Miltex System	SteriTite System
Indicated for use containing instruments to be sterilized in pre-vacuum (a.k.a. Hi-Vac) steam sterilizers	Yes	Yes
Intended to be re-used	Yes	Yes
Closed System	Yes	Yes
Sealed	Yes	Yes
Design		
Incorporates a filter system to permit entry of sterilant agent	Yes	Yes
Incorporates a filter system to prevent microbial migration during transport.	Yes	Yes
Materials		
Container	Aluminum alloy, Stainless Steel, & Silicone	Aluminum alloy, Stainless Steel, & Silicone

Performance Data:

A comparison of the non-clinical performance of the Miltex Rigid Sterilization Containers to the predicate device's.

Properties	Miltex System	SteriTite System
Performance Standards		
Conformance to appropriate AAMI standards	Yes, conforms to AAMI ST 77 Draft- *Containment Devices for Reusable Medical Device Sterilization*	Yes, conforms to AAMI ST 33- *Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for ETO Sterilization and Steam Sterilization in Health Care Facilities*
Validation Testing		
Pre-vacuum Steam	Yes	Yes
Load	Up to 16-lbs. (small) Up to 20-lbs. (med.) Up to 25-lbs. (large)	Up to 22-lbs.
Test Organisms/ Inoculated Product		
Inoculated Lumens	3-mm I.D. x 400-mm, metal and 3-mm I.D. x 200-mm, metal	Yes-- 2.2-mm I.D. x 457-mm, metal
Inoculated Stainless Steel Medical Devices	Yes	Yes (blades)

Conclusion:

The Miltex Rigid Sterilization Containers is substantially equivalent to the SteriTite Container (K023614).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2005

Mr. Lee Zagar
Vice President, Quality Assurance & Regulatory Affairs
Miltex, Incorporated
589 Davies Drive
York, Pennsylvania 17402

Re: K050570
Trade/Device Name: Miltex Rigid Sterilization container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: July 20, 2005
Received: July 21, 2005

Dear Mr. Zagar:

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.

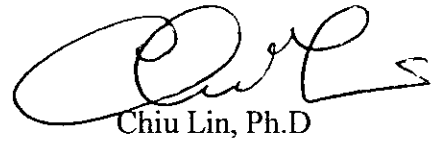
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K050570

Device Name: Miltex Rigid Sterilization Container System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K050570