JUN 3 - 2005

K041096

WAGNER

510(k) Summary

Regulatory Information:

Device Name:	Wrap, Sterilization
Proprietary Name:	Wagner SteriSet™ Sterilization System
Common:	Sterilization Container
Panel	80 (General Hospital)
Class:	II
ProCode:	FRG

Company Information:

Wagner GmBH
Schulstr. 16a
D-80634 Munich, Germany
Phone +49 (0) 89 163231
Fax +49 (0) 89 133099
Contact Name: Peter Wagner
Contact Title: Managing Director
Registration # 1000202929

Submission Correspondent:

Ms. Lara Simmons
Simcon International
22411 60th Street
Bristol, WI 53104
Phone: 847-682-0224
Fax: 262-843-4063
Email: Simcon1@att.net

Device Description

The containers are used for holding operating room instruments and/or textiles during vacuum-steam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. Reference Attachment 2 for instructions for use for the containers.

Design Features, which are identical to the above listed products, are as follows:

7. A 'hidden' lid that is a composite lid design that protects air/steam-permeable inner lid from direct physicals and biological challenges. The two lid components are separated by an air gap which allows air and steam to travel under the outer lid to the permeable portions of the inner lid where it enters (or exits) the container.

8. A valve plate that allows air/steam permeability
9. A gasket that is made of low durometer soft silicone rubber that is in the inner lid that provides a secure barrier seal between container lid and bottom. The gasket is secured when the outer lid is attached to the container bottom.
10. Two handles, one at either end of the container, have a silicone rubber covering for thermal insulation and ease of handling.
11. An aluminum standoff rim is riveted to the container bottom to protect from damage and facilitates stacking.
12. A thermostatic condensate drain consisting of a neoprene seal with a bimetallic strip for opening and a counterspring for closing. The drain allows the release of condensate from the interior of the container during sterilization, and is closed during storage and handling of the containers.

Technical Data:

3. Container Assembly: When sealed the container assembly allows penetration fo air and steam into and out of the container for sterilization of its contents. The container has three major metal components:
    a. Bottom – of deep drain aluminum, forms five sides of the container and seals to the inner lid by means of a gasket.
    b. Inner lid – with container bottom, provides the sealed container with a means for air/seam permeability. Steam enters through the annulus formed between the outer and inner lids by the sprung pressure plate. The pressure plate retains the filter (if required) and seals in the inner lid to the container bottom.
    c. Outer lid – protecs the inner lid from damage and/or contamination. Provides a mechanism to tlatch the inner lid to the container bottom.
4. Materials:
    a. Aluminum (99+% pure) with an anodized coating for corrosion-resistance, is the primary material of construction. Hardware is of AIS 17-7 CrNI Stainless steel or nickel plated brass. Lid sealing gasket and handle insulation is of silicone rubber.

Substantial Equivalence:

The containers are identical to the Medline (K010825) and AMSCO (K823902) in design, materials, and intended use. All containers (Medline and AMSCO included) are manufactured by Wagner GmBH..

Biocompatibility:

Biocompatibility data is not required for this product, as it has been legally marketed since 1982 and has a well-established history of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 - 2005

Wagner GmbH
C/O Ms. Lara N. Simmons
Simcon International
22411 60th Street
Bristol, Wisconsin 53104

Re: K041096
Trade/Device Name: Wagner Steriset Sterilization Container
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: May 20, 2005
Received: May 23, 2005

Dear Ms. Simmons:

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.

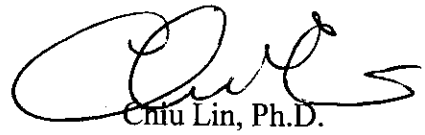
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K041096

Device Name: Wagner Steriest Containers

Indications For Use: The SteriSet Sterilizatoin Conatiner is intended to be used to ecnlose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility until used. The SterieSet Containers are designed for use with high-vacuum or pulse-vacuum steam sterilization systems. They are not suitable for gravity, gravity flash, or ethylene oxide (EO) gas cycles due to their "closed design".

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 K041096