K092437

MAR 2 5 2010

SECTION 5 510 (k) Summary

Company Name:	Codman & Shurtleff, Inc.
Company Address:	325 Paramount Drive Raynham, MA 02767
Establishment Registration No.:	1226348

Device Proprietary Name:	Codman® Sterilization Containers
Common Name:	Rigid Sterilization Container
Device Classification Name:	Sterilization wrap containers, trays, cassettes, and other accessories.
Classification Panel Name:	General Hospital
FDA Panel Number:	80
Product Code:	KCT
Proposed Device Class:	Class II per 21 CFR § 880.6850 Sterilization wrap
Predicate Device(s):	Miltex Rigid Sterilization Container System K072563
Device Description:	The Codman Sterile Container System is designed and manufactured on the basis of use to hospitals and operating rooms, where hygienic and sterile conditions are fully provided.
Indications for Use:	The CODMAN Sterilization Container System is indicated for use by hospitals and by health care facilities to: o organize and protect stainless steel, aluminum, and titanium general surgical instruments that will be sterilized o allow sterilization of the contained instruments by prevacuum steam sterilization (validated parameters shown in Table 1) o maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been compromised The system has not been tested for maintenance of sterility after transportation outside the health care facility.

The system is intended for use with stainless steel, aluminum, and titanium general surgical instruments.

The system is intended for use with lumen instruments as follows:

Lumen inner diameter	3 mm or larger
Lumen length	400 mm or less (medium and large size containers) 250 mm or less (small size containers)
Quantity	Up to 4 lumen instruments per container

The system is not intended for the sterilization of endoscopes.

For effective sterilization and drying of any size CODMAN Sterilization Container, the recommended maximum combined weight of the single container, lid, basket and basket contents is 25 lb. (11.3 kg). Please refer to Appendix A for a table of validated configurations of lids, bottoms, safety covers, and accessories.

Table 1
Sterilization Parameters

Cycle Type	Temperature	Exposure Time	Dry Time
Prevacuum	132 ° C	4 minutes	30 minutes

Performance Data

Testing has been completed and supports the safety and effectiveness of the proposed device for its intended use.

Official Contact:

Paul Amaral
International Regulatory Affairs Sr. Specialist
325 Paramount Drive
Raynham, MA 02767

Phone Number: (508) 828-3393 Facsimile Number: (508) 828-2777

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

MAR 25 2010

Mr. Paul Amaral
Regulatory Affairs Senior Specialist
Codman & Shurtleff, Incorporated
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K092437
Trade/Device Name: Codman Sterilization Containers
Regulation Number: 21CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: March 17, 2010
Received: March 18, 2010

Dear Mr. Amaral:

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

SECTION 4 Indications for Use

510(k) Number (if known): K092437

Device Name: Codman Sterilization Containers

Indications

The CODMAN Sterilization Container System is indicated for use by hospitals and by health care facilities to:

- organize and protect stainless steel, aluminum, and titanium general surgical instruments that will be sterilized
- allow sterilization of the contained instruments by prevacuum steam sterilization (validated parameters shown in Table 1)
- maintain the sterility of the contents for up to 180 days during storage and transport within the health care facility, as long as the integrity of the container has not been compromised

The system has not been tested for maintenance of sterility after transportation outside the health care facility.

The system is intended for use with stainless steel, aluminum, and titanium general surgical instruments.

The system is intended for use with lumen instruments as follows:

Lumen inner diameter	3 mm or larger
Lumen length	400 mm or less (medium and large size containers) 250 mm or less (small size containers)
Quantity	Up to 4 lumen instruments per container

The system is not intended for the sterilization of endoscopes.

For effective sterilization and drying of any size CODMAN Sterilization Container, the recommended maximum combined weight of the single container, lid, basket and basket contents is 25 lb. (11.3 kg). Please refer to Appendix A for a table of validated configurations of lids, bottoms, safety covers, and accessories.

Table 1 Sterilization Parameters			
Cycle Type	**Temperature**	**Exposure Time**	**Dry Time**
Prevacuum	132 ° C	4 minutes	30 minutes

Prescription Use: _____ _____ OR Over-The-Counter Use: ✓
(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)

)ivision Sign-Off)
ivision of Anesthesiology, General Hospital
ection Control, Dental Devices

10(k) Number: K092437