Allegiance
a Cardinal Health company

AUG 2 0 2002

K012931

SUMMARY OF SAFETY AND EFFECTIVENESS

Genesis™ STERRAD® Compatible Reusable Sterilization Container System

Manufacturer:	Allegiance Healthcare Corporation V. Mueller Business Unit 1430 Waukegan Road McGaw Park, IL 60085
Regulatory Affairs Contact	Lance Marconi 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3312
Date Summary Prepared:	August 30, 2001
Product Trade Name:	Genesis™ STERRAD® Compatible Reusable Sterilization Container System
Common Name:	Sterilization Container
Classification:	Sterilization Wrap
Predicate Device: **(K991023)**	SteriTite perforated base rigid reusable sterilization container system
Description:	The Allegiance Genesis™ STERRAD® Compatible Reusable Sterilization Container System is a reusable device which features an assortment of container designs and sizes, and inner basket and platform types.

Intended Use:

A sterilization container system, is a device intended to be used to enclose 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 of the enclosed device until used.

This container system is intended to be used in STERRAD®, ethylene oxide and pre-vacuum sterilization processes.

Substantial Equivalence:

The Allegiance Genesis™ STERRAD® Compatible Reusable Sterilization Container System is substantially equivalent to the SteriTite perforated base rigid reusable sterilization container system with SCF02-polypropylene non-woven disposable filter by Case Medical, Inc in that the:

- Intended use is the same
- Performance attributes are the same

Summary of Testing:

Sterilization Performance studies were conducted for the Genesis™ STERRAD® Compatible Reusable Sterilization Container System and all acceptance criteria were met.

Thirty-Day and One Hundred Eighty-Day Event Related Shelf Life Sterility tests were conducted. Results demonstrate that this product is in compliance with established standards, and is deemed acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2002

Mr. Lance Marconi
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road
McGraw Park, Illinois 60085

Re: K012931
Trade/Device Name: Genesis™ STERRAD® Compatible Reusable Sterilization Container System
Regulation Number: 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 5, 2002
Received: June 7, 2002

Dear Mr. Marconi:

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.

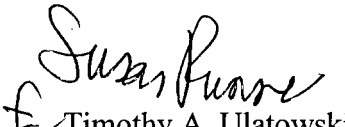
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance
a Cardinal Health company

510(k) Number (if known): **K012931**

Device Name: Genesis™ STERRAD® Compatible Reusable Sterilization Container System

Indications For Use: A sterilization container system is a device intended to be used to enclose 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 of the enclosed device until used.

This container system is intended to be used in STERRAD® 50, STERRAD® 100 and STERRAD® 100S, ethylene oxide and pre-vacuum sterilization processes.

Model Number:	**Model Description:**
CD1-4ST	Bottom, Half-Length, Perforated, 4", Lid, Half-Length
CD1-5ST	Bottom, Half-Length, Perforated, 5", Lid, Half-Length
CD1-6ST	Bottom, Half-Length, Perforated, 6", Lid, Half-Length
CD2-4ST	Bottom, Mid-Length, Perforated, 4", Lid, Mid-Length
CD2-5ST	Bottom, Mid-Length, Perforated, 5", Lid, Mid-Length
CD2-6ST	Bottom, Mid-Length, Perforated, 6", Lid, Mid-Length
CD3-4ST	Bottom, Full-Length, Perforated, 4", Lid, Full-Length
CD3-5ST	Bottom, Full-Length, Perforated, 5", Lid, Full-Length
CD3-6ST	Bottom, Full-Length, Perforated, 6", Lid, Full-Length
CD0-3ST	Bottom, Mini, Perforated, 3", Lid, Mini
CD0-4ST	Bottom, Quarter-Length, Perforated, 4", Lid, Quarter-Length
CD4-3ST	Bottom, Small Shallow, Perforated, 3", Lid, Small
CD4-5ST	Bottom, Small, Perforated, 5-1/2", Lid, Small

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or **Over-The Counter Use** _____
(Per 21 CFR 801.109)

Olivia S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices 6

510(k) Number: K012931