Aug 4, 2000

K983299

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085
847.473.1500
FAX: 847.785.2461

SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer:	Allegiance Healthcare Corporation V. Mueller Business Unit 1435 Lake Cook Road Deerfield, Illinois 60015
Regulatory Affairs Contact	Patricia Sharpe-Gregg 1500 Waukegan Road McGaw Park, Illinois 60085
Telephone:	(847) 578-3836
Date Summary Prepared:	September 2, 1998
Product Trade Name:	Allegiance Genesis™ Container System
Common Name:	Sterilization Container
Classification:	Sterilization Wrap
Predicate Device: (K844652)	C.A.S.E.™ Container System
Description:	The Allegiance Genesis™ Container System is a reusable device which features an assortment of container designs and sizes, and inner basket and platform types.
Intended Use:	The Allegiance Genesis™ Container 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 prevacuum steam and ethylene oxide sterilization processes.

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085
847.473.1500
FAX: 847.785.2461

Substantial Equivalence:	The Allegiance Genesis™ Container is substantially equivalent to the Allegiance C.A.S.E™ Container System, Dental, Medical Instrument Cases & Cassettes by Sterilization Cassette Systems, Inc. and the Aesculap Sterilization Container in that the: - Intended use is the same - performance attributes are the same
Summary of Testing:	Sterilization performance studies were conducted and all acceptance criteria were met. Thirty-Day and Ninety-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 4 2000

Ms. Patricia Sharpe-Gregg
Director
Allegiance Healthcare Corporation
1500 Waukegan Road, Building MPWM
McGaw Park, Illinois 60085

Re: K983299
Trade Name: Allegiance Genesis Container System
Regulatory Class: II
Product Code: FRG
Dated: May 22,2000
Received: May 23, 2000

Dear Ms. Gregg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085 USA
847-473-1500
FAX: 847-785-2461

510(k) Number (If known): Unknown

Device Name: Allegiance Genesis™ 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 prevacuum steam and ethylene oxide sterilization processes.

(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 X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983299