

AUG 25 1998

K983719



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

ATTACHMENT F

SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturer: Allegiance Healthcare Corporation
V. Mueller Business Unit
1435 Lake Cook Road
Deerfield, IL 60015

Regulatory Affairs Contact: Patricia Sharpe-Gregg
1500 Waukegan Road
McGaw Park, Illinois 60085

Telephone: (847) 578-3636

Date Summary Prepared: October 16, 1998

Product Trade Name: Allegiance BioShield® Express™ Sterilization Wrap

Common Name: CSR Wrap or Sterilization Wrap

Classification: Sterilization Wrap

Predicate Device:
(K770933) Allegiance BioShield® Sterilization Wrap

Description: The Allegiance BioShield® Express™ Sterilization Wrap is composed of a wet formed non-woven cellulose fiber with acrylic binders.

Intended Use: The Allegiance BioShield® Express™ Sterilization Wrap is a single-use, non-sterile device. It is 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 wrap is intended for use in prevacuum steam sterilization processes.



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Substantial Equivalence:

The Allegiance Allegiance BioShield® Express™ Sterilization Wrap is substantially equivalent to the Dextex II Sterilization Wrap and the Kinguard™ Sterilization in that the:

- intended use is the same
- performance attributes are the same

The Allegiance BioShield® Express™ Sterilization Wrap is substantially equivalent to the Allegiance BioShield® Sterilization Wrap in that the:

- intended use is the same
- material composition is the same
- performance attributes are the same

Summary of Testing:

The material used in the composition of this sterilization wrap was evaluated and tested as required in ISO Standard 10993 Part 1. The material was subjected to skin sensitization, intracutaneous reactivity and cytotoxicity testing. Physical and performance testing was completed including sterilization performance testing. This product is in compliance with established standards, where applicable, and is deemed acceptable for its intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 1999

Ms. Patricia Sharpe-Gregg
Manager, Regulatory Affairs
Allegiance Healthcare Corporation
1500 Waukegan Road, Building MP-WM
McGaw Park, Illinois 60085

Re: K983719
Trade Name: BioShield® Express™ Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 15, 1999
Received: July 16, 1999

Dear Ms. Sharpe-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 (Pre-market 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:

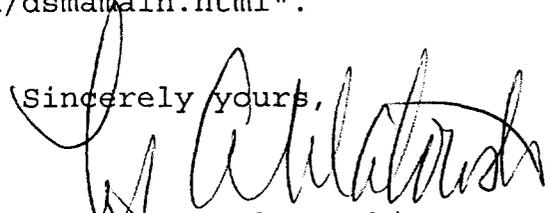
Page 2 - Ms. Sharpe-Gregg

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



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510(k) Notification Express Sterilization Wrap
V. Mueller Business Unit
Page 1 of 1

510(k) Number (if known): Unknown K983719

Device Name: Bioshield® Express™ Sterilization Wrap

Indications For Use: The Bioshield® Express™ Sterilization Wrap 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 wrap is intended for use in prevacuum steam sterilization processes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or  Over-The Counter Use

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983719