

JUL 10 1998



*Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461*

K 981818

XII. SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Trilaminate Drapes**

Manufacturer: Allegiance Healthcare Corporation
Convertors® Operations
One Butterfield Trail
El Paso, Texas 79906

Regulatory Affairs Contact: Sharon Robbins
Allegiance Healthcare Corporation
1500 Waukegan Road MPWM
McGaw Park, IL 60085

Telephone: (847) 785-3311

Date Summary Prepared: May 1998

Common Name: Convertors® Trilaminate Drapes

Classification: Class II per 21CFR § 878.4370

Predicate Device: Convertors® Drape Materials

Description: These drapes will be composed of nonwoven fabrics adhesively laminated to a synthetic polymer film. The film is a finely embossed blended polyethylene construction. The drapes also have clear polyethylene side panels on either end of the drapes.



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XII. SMDA REQUIREMENTS (continued)

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Trilaminate Drapes**

Intended Use: The Convertors® Trilaminate Drapes are devices intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

Substantial Equivalence: The Convertors® Trilaminate Drapes are substantially equivalent to the Convertors® drape materials in that:

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

Summary of testing: All materials used in the fabrication of the Convertors® Trilaminate drapes were evaluated through biological qualification safety tests as outlined in in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and intracutaneous reactivity. These materials also were tested in accordance with industry recognized test methods for hydrostatic head, impact penetration, synthetic blood penetration (ASTM 1670-1995), Phi X174 (ASTM 1671-1995), Grab Tensile, Basis Weight, and flammability, Class 1. These materials have met the requirements of the identified tests and were found to be acceptable for the intended use.

XIII. SAMPLE

A prototype drawing of a drape has been provided (enclosed) to visually assist with the review. (*See Appendix K*).

XIV. KIT CERTIFICATION

This submission is for drapes only. This submission is not for a kit or tray. As with the predicate device, these drapes will be placed in kits and trays that are already cleared through the premarket notification process or are exempt per the Convenience Kit Guidance dated 5/97 which allow drapes to be placed in kits and trays.

XIV. 21 CFR 807.95 -CONFIDENTIALITY

Allegiance Healthcare Corporation regards its intent to market the Convertors® drape material as confidential commercial information. We have not divulged this intent to market information to anyone other than Allegiance employees and even then on a need-to-know basis. Therefore, we request that FDA treat this information in a confidential manner.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon Robbins
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road MPWM
McGaw Park, Illinois 60085-6787

Re: K981818
Trade Name: Convertors® Trilaminate Drapes
Regulatory Class: II
Product Code: KKK
Dated: May 21, 1998
Received: May 22, 1998

Dear Ms. Robbins:

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.

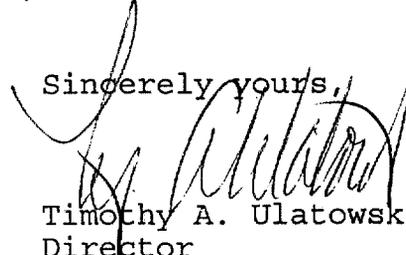
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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: 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) Number (if known): Unknown K981818

Device Name: Convertors® Trilaminate Drapes

Indications For Use: The Convertors® Trilaminate Drapes are devices intended to be used as a protective patient covering, such as to isolate a site of surgical incision from microbial and other contamination.

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)

Chen S. Lim
 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices
 510(k) Number K981818