

JAN 12 2000



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

K 99 3795

## SMDA REQUIREMENTS

### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS Convertors® Surgical Drapes

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

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

Telephone: (847) 785-3311

Date Summary Prepared: September, 1999

Common Name: Convertors® Surgical Drapes

Classification: Class II per 21CFR § 878.4370

Predicate Device: Isolyser Enviroguard Drapes.

Description: The drapes are comprised of a single layer of degradable spunlaced nonwoven fabric with various reinforcements. The fiber is water soluble in temperatures above approximately 190 degrees F.

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



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## **SMDA REQUIREMENTS (continued)**

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

**Substantial Equivalence:**

The Convertors® Surgical drapes are substantially equivalent to the Isolyser Enviroguard dapes in that:

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

**Summary of testing:**

All materials used in the fabrication of this Convertors® Surgical drapes were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and irritation/ intracutaneous reactivity. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JAN 12 2000**

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

Re: K993795  
Trade Name: Convertors® Surgical Drapes  
Regulatory Class: II  
Product Code: KKK  
Dated: November 8, 1999  
Received: November 9, 1999

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

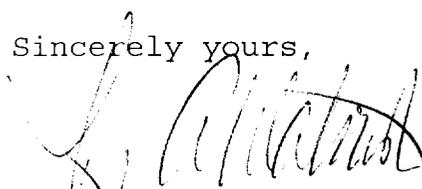
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obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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" (21 CFR 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/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  
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510(k) Number (if known): Unknown

Device Name: Convertors® Surgical Drapes

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The Counter Use X

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Chin S. Kim  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K993795