

MAY 27 1997



K970554

*Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460*

XII. SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® SMS Drapes and Accessories**

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

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

Telephone: (847) 785-3311

Date Summary Prepared: January, 1997

Common Name: Convertors® SMS Drapes and Accessories

Classification: Class II per 21CFR § 878.4370

Predicate Device: Kimberly-Clark Evolution III Drapes

Description: These drapes will be composed of a trilaminate Spunbond/Meltblown/Spunbond Polyolefin nonwoven fabric with an adhesively laminated reinforcement fabric around the fenestration.



Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2460

XII. SMDA REQUIREMENTS (continued)

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors[®] SMS Drapes and Accessories**

Intended Use: The Convertors[®] SMS Drapes and Accessories 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[®] Drape material is substantially equivalent to the Kimberly-Clark SMS (Evolution III) drapes:

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

Summary of testing: All materials used in the fabrication of this Convertors[®] drape materials were evaluated through biological qualification safety tests as outlined in the ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, sensitization, and irritation/intracutaneous reactivity. Flammability testing was performed. The physical tests performed on the SMS material were hydrostatic head, impact penetration, alcohol repellency, elmendorf tear and grab tensile. These materials have met the requirements of the identified tests and were found to be acceptable for the intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 1997

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

Re: K970554
Trade Name: Convertors SMS Drapes
Regulatory Class: II
Product Code: KKX
Dated: April 1, 1997
Received: April 29, 1997

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 (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 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 obligation you might have under sections 531 through 542 of

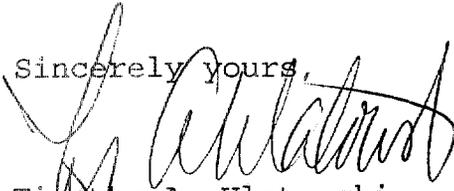
Page 2 - Ms. Robbins

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
 1500 Waukegan Road
 McGaw Park, Illinois 60085-6787
 847.473.1500
 FAX: 847.785.2460

510(k) Number (if known): Unknown K970554

Device Name: Convertors® SMS Drapes and ~~Accessories~~

Indications For Use: The Convertors® SMS Drapes and ~~Accessories~~ are 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)

Chin S. Lim
 (Division Sign-Off)
 Division of Dental, Infection Control,
 and General Hospital Devices

1

510(k) Number K970554