K023419

Allegiance
a Cardinal Health company

Allegiance Healthcare
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FEB 1 1 2003

SMDA REQUIREMENTS

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

Sponsor:	Allegiance Healthcare Corporation 1500 Waukegan Road MPWM McGaw Park, IL 60085
Regulatory Affairs Contact:	Sharon Nichols
Telephone:	(847) 785-3311
Date Summary Prepared:	September, 2002
Common Name:	Convertors®Trilaminate Drapes
Classification:	Class II per 21CFR § 878.4370
Predicate Device:	Convertors®Trilaminate Drapes
Description:	These drapes will be comprised of an outer and inner layer of polyolefin-based nonwovens with an inner layer of polyolefin-based film. Several drapes will also have clear polyethylene side panels on either end of the drapes.

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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® trilaminate 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. These materials have met the requirements of the identified tests and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2003

Ms. Sharon Nichols
Regulatory Affairs Manager
Allegiance Healthcare Corporation
1500 Waukegan Road, Building WM
McGaw Park, Illinois 60085

Re: K023419
Trade/Device Name: Convertors® Trilaminate Drapes
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: November 14, 2002
Received: November 15, 2002

Dear Ms. Nichols:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K023419

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 _____
(Per 21 CFR 801.109)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023419