OCT 0 2 2002

Allegiance

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

K023167

## SMDA REQUIREMENTS

### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
### Convertors® Breathable Surgical Gowns and Breathable Sleeve Surgical Gowns

| | |
|---|---|
| Manufacturer: | Allegiance Healthcare Corporation<br>One Butterfield Trail<br>El Paso, Texas 79906 |
| Regulatory Affairs Contact: | Sharon Nichols<br>1500 Waukegan Road MPWM<br>McGaw Park, IL 60085 |
| Telephone: | (847) 785-3311 |
| Date Summary Prepared: | September, 2002 |
| Common Name: | Convertors®Breathable Surgical Gowns and Breathable Sleeve Surgical Gowns |
| Classification: | Class II per 21CFR § 878.4040 |
| Predicate Device: | Convertors® Breathable Surgical Gowns. |
| Description: | The Breathable Surgical Gown consists of an outer and inner layer of spunmelt polyolefin nonwoven fabric with a middle layer of breathable monolithic film throughout the entire gown. The Breathable Sleeve Surgical Gown consists of sleeves containing a an outer and inner layer of spunmelt polyolefin nonwoven fabric with a middle layer of breathable monolithic film with a gown body comprised of spunmelt nonwoven (SMS) with a polyolefin-based film reinforcement. |

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## SMDA REQUIREMENTS (continued)

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

| | |
|---|---|
| Intended Use: | Surgical apparel are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material. |
| Substantial Equivalence: | The Convertors® gowns are substantially equivalent to the Convertors® Breathable gowns in that:<br>- the intended use is the same<br>- the performance attributes are similar |
| Summary of testing: | All materials used in the fabrication of this Convertors®Breathable Gowns 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. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2002

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

Re: K023167
Trade/Device Name: Convertors® Breathable Surgical Gowns
Regulation Number: 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: 79 FYA
Dated: September 20, 2002
Received: September 23, 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.

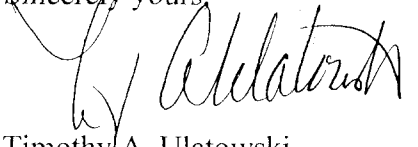
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618 . 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

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510(k) Number (if known): ~~Unknown~~ K023167

Device Name: Convertors®Breathable Surgical Gowns

Indications For Use: The Convertors®Breathable Surgical Gowns are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.

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(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)

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

510(k) Number: K023167