

FEB 1 8 2000

K 994244



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

SMDA REQUIREMENTS

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

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 Gowns

Classification: Class II per 21CFR § 878.4040

Predicate Device: Isolysr Industries Enviroguard Surgeons Gowns.

Description: The gowns are comprised of a single base layer of degradable spunlaced nonwoven fabric in gown configurations of unreinforced, fabric reinforced and poly-reinforced. The fabric reinforced gown contains an additional layer of spunlaced nonwoven fabric in the chest and sleeves area. The poly-reinforced gown contains an additional layer of polyolefin film in the chest and sleeves of the gown.



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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS Convertors® 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® Surgical gowns are substantially equivalent to the Isolyser Enviroguard gowns 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 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 primary skin irritation. These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.



AUG 18 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K994244
Trade/Device Name: Convertors® Surgical Gowns
Regulation Number: 878.4040
Regulation Name: Surgical apparel
Regulatory Class: II
Product Code: FYA
Dated: December 14, 1999
Received: December 16, 1999

Dear Ms. Robbins:

This letter corrects our substantially equivalent letter of February 18, 2000.

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 (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 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 continue 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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure: IFU Statement



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510(k) Number (if known): Unknown **K 994244**

Device Name: Convertors® Surgical Gowns, **sterile**

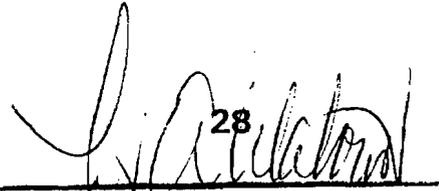
Indications For Use: The Convertors® Surgical Gowns are devices intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate material.

(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 Dental, Infection Control,
 and General Hospital Devices
 510(k) Number **K 994244**