K992951

SEP 22 1999

Allegiance

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

XII. SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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:	July, 1999
Common Name:	Convertors® Surgical Gowns
Classification:	Class II per 21CFR § 878.4040
Predicate Device:	Convertors® Optima Gowns.
Description:	The gowns are comprised of a single layer of spunlaced nonwoven fabric with a polyethylene reinforcement in the chest area and a breathable monolithic film in the sleeves.

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XII. SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® 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® gowns in that: - the intended use is the same - the performance attributes are the similar
Summary of testing:	All materials used in the fabrication of this Convertors® 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

SEP 22 1999

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

Re: K992951
Trade Name: Covertors® Surgical Gowns
Regulatory Class: II
Product Code: FYA
Dated: August 31, 1999
Received: September 1, 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 (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

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) 594-4690. 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,

Susan Runner

FA 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

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510(k) Number (if known): ~~Unknown~~ K992951

Device Name: Convertors® Surgical Gowns

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.

Olivia S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992951

(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)