

AUG 24 1998



*Allegiance Healthcare Corporation
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McGaw Park, Illinois 60085-6787
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K982369

XII. SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS Convertors® Spunbonded, Flashspun Polyolefin 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® Spunbonded, Flashspun Polyolefin gowns are substantially equivalent to the Convertors® Optima standard, fabric- and poly-reinforced 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® Spunbonded, Flashspun Polyolefin 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.

XIII. SAMPLE

A drawing of the standard, fabric- and poly-reinforced gowns are enclosed to visually assist with the review. (*See Appendix D*).

XIV. KIT INFORMATION

Each gown is packaged with a towel. The towel is the same towel that is currently placed in our gown packs. This towel has been used safely and effectively for many years as a component of the gown pack. This premarket notification (510(k)) is to introduce standard, fabric and poly-reinforced gowns constructed of Spunbonded, Flashspun Polyolefin fabric. There is no change to the towel contained within this pack.

XV. 21 CFR 807.95 -CONFIDENTIALITY

Allegiance Healthcare Corporation regards its intent to market the Convertors® Spunbonded, Flashspun Polyolefin gown as confidential commercial information. Allegiance Healthcare Corporation has not divulged this intent to market information to anyone other than Allegiance employees and even then on a need-to-know basis. Therefore, we request that FDA treat this information in a confidential manner.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 24 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K982369
Trade Name: Convertors® Spunbonded, Flashspun
Polyolefin Gowns, Sterile
Regulatory Class: II
Product Code: FYC
Dated: July 1, 1998
Received: July 7, 1998

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 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). 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 (Pre-market 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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

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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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

S. Autumn for

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

Enclosure



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510(k) Number (if known):

K 982369

Device Name:

Convertors® Spunbonded, Flashspun Polyolefin Gowns, *Sterile*

Indications For Use:

The Convertors® Spunbonded, Flashspun Polyolefin 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 _____
 (Per 21 CFR 801.109)

or

Over-The Counter Use X

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

510(k) Number K 982369