

DEC 23 1996



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K964125

XII. SMDA REQUIREMENTS

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Convertors® Drapes and Leggings**

Manufacturer: Allegiance Healthcare Corporation
Convertors® Operations
One Butterfield Trail
El Paso, Texas 79906

Regulatory Affairs Contact: Sharon Robbins
Allegiance Healthcare Corporation
1500 Waukegan Road MPK
McGaw Park, IL 60085

Telephone: (847) 785-3311

Date Summary Prepared: September, 1996

Common Name: Convertors® Drapes and Leggings

Classification: Class II per 21CFR § 878.4370

Predicate Device: Convertors® Drape Materials

Description: These drapes and leggings will be composed of a nonwoven fabric adhesively laminated to a synthetic polymer film. The nonwoven contains adhesively bonded polyester fibers. The film is a 1.25 mil finely embossed blended polyethylene construction.



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XII. SMDA REQUIREMENTS (continued)

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

Intended Use: The Convertors® Drapes and Leggings 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® Drapes and Leggings are substantially equivalent to the Convertors® legging 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 this Convertors® drapes and leggings 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 irritation/intracutaneous reactivity. These materials also met the requirements of hydrostatic head, impact penetration, synthetic blood penetration (ASTM 1670-1995), Phi X174 (ASTM 1671-1995) Trapezoid Tear, Grab Tensile, Mullen Burst, Basis Weight, and flammability, Class 2. These materials have met the requirements of the identified tests and were found to be acceptable for the intended use.