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MAR 27 1997



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**XII. SMDA REQUIREMENTS**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
Convertors® Impervious Shoe Covers**

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: March, 1997

Common Name: Convertors® Impervious Shoe Covers

Classification: Class I per 21CFR § 878.4040

Predicate Device: Kimberly-Clark X-Tra Traction Impervious Boot

Description: These shoe covers will be composed of a nonwoven fabric hot melt adhesively laminated to a synthetic polymer film. The nonwoven is a 1.5 osy blue spunbonded polypropylene. The film is a 1.25 mil embossed, polyethylene.



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**XII. SMDA REQUIREMENTS (continued)**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
Convertors® Impervious Shoe Covers**

**Intended Use:** The Convertors® Impervious Shoe Covers 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® Shoe cover material is substantially equivalent to the Kimberly- Clark X-Tra Traction Impervious Boots 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® shoe cover materials were evaluated through physical qualification tests. The tests performed on the Shoe Covers were Flammability, Hydrostatic head, Synthetic Blood Penetration, Phi X174 Penetration, Alcohol Repellency, Trapezoid Tear, Grab Tensile, Mullen Burst, Elmendorf Tear, Basis Weight, Thickness, Coefficient of Friction, Electrostatic Decay and Abrasion. These shoe covers have met the requirements of the applicable standards and were found to be acceptable for the intended use.