

SEP 17 1996

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**SUMMARY OF SAFETY AND EFFECTIVENESS**

**NAME OF FIRM:** DePuy Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

**510(k) CONTACT:** Cheryl Hastings  
Manager, Pre-clinical Device Evaluation

**TRADE NAME:** DePuy Sterile View® Barrier Hood/Gown with  
Hytrel®

**CLASSIFICATION:** 878.4040 Surgical apparel

**DEVICE PRODUCT CODE:** 79 FYA

**SUBSTANTIALLY  
EQUIVALENT DEVICES:**

- ▶ DePuy Sterile View Barrier Hood/Gown UV
- ▶ Stackhouse Freedom Mark III Surgical Helmet System
- ▶ Baxter Converters Breathable Gown

**INTENDED USE AND DEVICE DESCRIPTION:**

The Sterile View Barrier Hood/Gown with Hytrel is intended as disposable surgical apparel 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.

The Barrier Hood/Gown with Hytrel is a sterile surgical gown, manufactured from Dexter paper and Sontara polyester fabric with a Hytrel polymeric coating. The Dexter paper is used for the hood and gown back. The Sontara/Hytrel material is used on the gown front and sleeves. A molded, polycarbonate face shield is sealed to the hood material. The Sontara/Hytrel material is fluid resistant but vapor transmissive. The gown therefore protects the wearer from fluid borne pathogens, while maintaining "breathability". The Barrier Hood/Gown with Hytrel is available in three sizes: size 1, size 2 and size 2 long. Testing has shown that the Sontara/Hytrel material of the Barrier Hood/Gown with Hytrel passes ASTM standard tests ES-21 for resistance to synthetic blood and ES-22 for resistance to penetration by blood borne pathogens using viral penetration as a test system.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy Sterile View Barrier Hood/Gown with Hytrel is identical in design and intended use to the DePuy Sterile View Barrier Hood UV. The only difference between these two products is that the material of the hood/gown has been changed from a polyester/wood pulp blend with a polyethylene coating to paper and polyester with a Hytrel polyester polyether coating. The primary advantage of the Hytrel coated material is that it is more breathable (and therefore more comfortable) than the previous material, but is still an effective barrier against fluids and microorganisms.

The Sterile View Barrier Hood/Gown with Hytrel is also similar in design and intended use to the Stackhouse Freedom III Toga Gown and the Baxter Converters Breathable Gown.

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