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**SUMMARY OF SAFETY AND EFFECTIVENESS**

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

AUG - 9 1996

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

**TRADE NAME:** DePuy Disposable Filter/Hood

**COMMON NAME:** Sterile surgical hood

**CLASSIFICATION:** 878.4040 Surgical apparel

**DEVICE PRODUCT CODE:** 79 FYA

**SUBSTANTIALLY EQUIVALENT DEVICES:**

- ▶ Stryker Steri-Shield Personal Protection System
- ▶ DePuy Sterile View Disposable Hood/Gown

**DEVICE DESCRIPTION AND INTENDED USE:**

The DePuy Disposable Filter/Hood is a single use, disposable hood with faceshield. The hood is constructed of Dexter paper with spun polypropylene filter media located at the top and back of the hood. The DePuy hood is designed to fit over the Stryker Steri-Shield helmet so that all intake and exhaust air passes through the filter material.

The DePuy Disposable Filter/Hood is intended to be used with the Stryker Steri-Shield System 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.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The DePuy Disposable Filter/Hood is designed to be identical to the Stryker Steri-Shield Hood. The DePuy Filter/Hood and the Stryker Hood have the same hood and faceshield design, the same filter location and the same intended use. The only difference between the two hoods are the materials from which they are constructed. The material of the DePuy Filter/Hood (Dexter paper) is the same as the material used for the DePuy Sterile View Disposable Hood/Gown. Comparative testing shows that the filtering efficiency of the DePuy filter material is as good as or better than the Stryker filter material for all particle sizes and flow rates tested.