



**Presbyterian Hospital**  
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**SUMMARY OF SAFETY AND EFFECTIVENESS**

January 21, 1997

K970286

1. **Regulatory Information**

**Device Name:** Surgical Procedure Packs  
**Proprietary:** Presbyterian Linen Surgical Procedure Packs  
**Common :** Surgical Packs  
**Classification:** Surgical Procedure Packs

2. **Submitted on behalf of Presbyterian Linen by:**

**Medline Industries, Inc.**  
**One Medline Place**  
**Mundelein, IL 60060**  
**Phone:** (847) 949-2639  
**Fax:** (847) 949-2643  
**Contact Person:** Lara N. Simmons  
**See Attached Letter of Authorization**

**Presbyterian Linen Services' Surgical Packs are substantially equivalent to the following:**

1. **K932522 AMSCO Sterile Recoveries Surgical Packs**
2. **K935199 Associated Hospital Services, Inc. Surgical Packs**
3. **K930700 Medline's Repeat Performance Surgical Pack System**

**Presbyterian Linen's Surgical Packs are virtually identical to the predicate devices listed above. The gowns, towels and drapes are of the same material and construction. There are no technological differences between the Presbyterian Linen packs and the predicate devices.**

**Device Description**

**Presbyterian Linen Services Surgical Packs are packs composed of reusable gowns, drapes, and toweling, the specifics of which are tailored to the customer's specifications for that procedure.**

**Intended Use:**

**Presbyterian Linen Services Surgical Packs are intended to be used in various surgical procedures. The packs provide sterile gowns, drapes and towels to be used during procedures to protect both the surgical patient and the operating room personnel from transfer of microbial and other contamination. Surgical towels provide additional absorption of blood and body fluids when used to square off a surgical site, or may be used by operating room personnel for drying of hands after scrubbing.**

*The Whole Approach To Health.*