

FEB 27 1997

K962666

**SMDA-1990
510(k) Summary -- K962666**

In response to the requirements addressed by the SMDA of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based. Substantial equivalence for the Bemiss Jason Surgical Gowns (reinforced and non-reinforced) is claimed due to material similarities, intended uses and safety/effectiveness.

A. Submitted by:

Bemiss Jason / Triad Medical Division
405 Walnut Street
PO Box 1436
Waynesville, NC 28786
Phone: 704-452-1919
Fax: 704-452-3702

B. Contact:

Sandra L. McGee
Quality Assurance/Compliance Officer

C. Submission Date: July 03, 1996

D. Common or Usual Names:

Sterile Surgical gown
Non - Sterile Surgical gown

E. Trade or Proprietary Names:

Bemiss Jason Sterile Surgical Gown - Sontara®
Bemiss Jason Sterile Surgical Gown - Dexter®
Bemiss Jason Sterile Surgical Gown - Securon®

Bemiss Jason Non-Sterile Surgical Gown - Sontara®
Bemiss Jason Non-Sterile Surgical Gown - Dexter®
Bemiss Jason Non-Sterile Surgical Gown - Securon®

Bemiss Jason Reinforced Sterile Surgical Gown - Sontara®
Bemiss Jason Reinforced Sterile Surgical Gown - Dexter®
Bemiss Jason Reinforced Sterile Surgical Gown - Securon®

Bemiss Jason Reinforced Non-Sterile Surgical Gown - Sontara®
Bemiss Jason Reinforced Non-Sterile Surgical Gown - Dexter®
Bemiss Jason Reinforced Non-Sterile Surgical Gown - Securon®

All Surgical Gowns would be available in Large and X-Large

SMDA-1990 -- 510(k) Summary (Continued)
K962666
Page 2

F. Intended Use

Disposable / Single Use Only

Surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and operating room personnel.

G. Summary

The substantial equivalence (SE) is primarily based upon surgical gowns presently manufactured by Isolyser (Mars White Knight) composed of an S/M/S trilaminate polypropylene spunbond outers / meltblown (polypropylene) inner layer. This fabric has shown fluid and alcohol repellency. Other referenced materials have also been shown to be fluid and alcohol repellent. Physical properties comparisons have shown that not only is one of the materials identical, the other materials have similar properties. All fabrics identified have previously been on the market.

Intended uses for these materials by Bemiss Jason is consistent with current (existing) usage for surgical gowns.

Safety and effectiveness evaluation of the fabric combinations have been performed by the material manufactures and Bemiss Jason. These evaluations have shown the materials to be colorfast and non cytotoxic. Preliminary ETO residual testing has shown to be well below the 1978 FDA proposed ETO residual guidelines. Some manufactures have shown their materials to be free of skin irritation and sensitization. Flammability classification has been determined as Class I.

In summary, the materials referenced in this SE submission for 510(k) is not new, nor is it for a new intended use. The materials have been widely available and used as surgical gowns. Manufacturers are currently shaping this material into gowns in both reinforced and non-reinforced styles. Physical, aesthetic, tactile and functional qualities of the material selected for the Bemiss Jason Surgical Gowns have been analyzed and evaluated. The materials are safe for both providers and patients and effective in function when used with standard normal intended use.