

M. SAFE MEDICAL DEVICES ACT OF 1990 STATEMENT OF SAFETY AND EFFECTIVENESS.

"510(k) Summary"

K 964256

MAY - 6 1997

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Trade Name : "Cygnus Instrument Protectors"
Common Name: Tray liners, instrument pouches
Classification Name: Sterilization wrap, pack
sterilization wrapper, bag or
accessories (per 21 CFR section
880.6850).

Predicate device:
Manufacturer

Devon Industries,
14569 Titus Street, Panorama City, California 91402
9530 Desoto Drive, Chatsworth, California 91311

Product - Devon Tiprotectors, tray pads and liners
510(k) Number - K771123
General and Plastic Surgery Device Panel
Classification - Class II
Regulatory Citation - 21 CFR ch 1 (4-1-95)

Product Description

The "Cygnus Instrument Protectors" liners and pouches are constructed with reticulated polyurethane ester foam. The material's open cell structure allows for the free flow of air, moisture and heat and is virtually free of particulate matter. The variety of sizes and shapes allows for greater flexibility in padding the instruments. Tray liners are available in precut sheets and rolls. The pouches are available in three sizes of single pouches and two sizes of multi pouch rolls. The pouches are formed by heat sealing the edges and seams. Each product is available in individual boxes as well as bulk case packaging. The products are shipped and marked as "non sterile" and "disposable". Each box is marked with a control lot number and universal bar code.

Summary: Intended Use

The primary purpose of the device is to protect surgical instruments during sterilization, storage and transportation to the surgical suite. This product is intended to be used by hospital staff during the preparation of the sterile instrument kits.

- The liners are first placed into the empty sterilization tray.
- The instruments are then placed onto the Cygnus liner (or in the pouch) and the trays are wrapped in CSR wrap using conventional wrapping methods.
- Cygnus tray liners are to be used with steam autoclave sterilization only at temperature settings ranging between - 121° C to 134 °C.
- The sterile wrapped kit remains closed until arrival within the sterile prepped operating room.
- The liners may continue to be used during the procedure as a sterile field on which to place instruments.
- Upon the completion of the procedure the liners are disposed of in accordance with applicable medical waste regulations.

Technological Characteristics

The technological characteristics of the Cygnus Instrument Protectors are identical to the predicate devices, as well as a number of other manufacturers producing this type of product. The tensile strength (30 lbs. psi), elongation (200%), tear strength (4.0 lbs. psi), density (1.9 lb./cu. ft.) and porosity (50Pore per sq. in.) all define this product as being appropriate and consistent with the intended use of the product.