

K 955872

510 (k) SUMMARY

MAR 12 1996

I. ADMINISTRATIVE

Submitter: Medal International Sales Company, LLC
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Date of Preparation: December 26, 1995

II. DEVICE NAME

Proprietary Name: Volmed™ Operation Drape
Common Name: Sterile Surgical Incise Drape
Classification Name: Sterile Surgical Drape
Regulatory Class: Class II Device
Product Code: 79KKX

III. PREDICATE DEVICE

Steri-Drape® Surgical Incise Drapes, legally marketed prior to May 28, 1976 by 3M Company.

IV. DEVICE DESCRIPTION

The Volmed Operation Drape is a sterile incise drape composed of a transparent mat polyurethane film coated on one side with an acrylic medical grade adhesive, supported by peelable white, silicon coated, double sided polyethylene protected release paper. The other side of the polyurethane film is protected by a polyethylene film which is removed after application of the drape to the surgical site.

Volmed Operations Drapes are supplied in 10 cm x 10 cm, 10 cm x 20 cm, 20 cm x 20 cm, 20 cm x 40 cm and 30 cm x 60 cm sizes in individual packages sterilized by gamma irradiation.

The biocompatibility of the device has been established by *in vitro* cytotoxicity, subcutaneous implantation (guinea pig), and dermal irritation (rabbit) tests. A repeat insult patch test in human volunteers showed that the material does not induce irritation or allergic contact dermatitis. In addition, a microbial permeability study with *S. aureus* was performed to demonstrate the effective performance of the drape as a bacterial barrier.

V. INTENDED USE

As a protective patient covering during surgical procedures, such as to isolate a site of surgical incision from microbial and other contamination.

VI. CONCLUSION

The technological characteristics of the Volmed Operation Drape are the same as those of predicate devices, such as the Steri-Drape® Surgical Incise Drape (3M Company). Biocompatibility and performance testing of the Volmed Operation Drape have demonstrated topical safety as well as effective microbial barrier performance. Accordingly, Medal International Sales Company has concluded that the Volmed Operation Drape is safe and effective for its intended use and performs at least as well as legally marketed predicate devices, such as the Steri-Drape® Surgical Incise Drape (3M Company).