

NOV 20 1996

510(k) Summary (K963809)**Submitter:** Kappler USA, 70 Grimes Drive, Guntersville, AL 35976**Prepared:** September 20, 1996**Contact:** Philip C. Mann**Device Name:** Totally Encapsulated (TE) Surgical Gown/Hood**Proprietary Name:** COOL-ZONE**Classification Name:** Gown, Surgical

The COOL-ZONE System is either a gown or hood that are similar to the Kappler Pro/Vent Surgical Gown which was the subject of Premarket Notification #K932694. The fabric in the COOL-ZONE gown and hood is identical to the fabric in the Pro/Vent Surgical Gown.

Gown and Hood

The surgical gown and hood are similar in design and composition to the Kappler Pro/Vent Surgical Gown identified in premarket notification #K932694.

The Pro/Vent TE Gown and Hood are constructed from the same fabric as the predicate device. The design of the gown differs in that the garment provides totally encapsulated protection to the wearer. Total encapsulation means total coverage of the entire upper body, thus providing greater protection than conventional surgical apparel. The TE Gown utilizes a mylar face shield for visibility. A zipper is located in the back of the garment. The TE Hood provides the same level of face and head protection, but does not extend down as far on the body. It will typically be worn with another surgical gown.

The TE Gown is intended to provide the wearer an increased level of blood and other body fluid protection during certain surgical procedures that result in excessive blood exposures by providing total encapsulation.

The technological characteristics of the Kappler Pro/Vent Surgical Gown and the Pro/Vent TE Gown or Hood are identical. The non-clinical performance data is summarized below.

The gown and hood may be used with air supplied cooling systems.

CHARACTERISTIC	PRO/VENT GOWN	PRO/VENT TE
Material Composition	100% Polypropylene	100% Polypropylene
Fabric Configuration	Trilaminate	Trilaminate
Barrier Layer	Microporous Film	Microporous Film
Composite Weight	2.1 oz/square yard	2.1 oz/square yard
Hydrostatic Head	43 inches	43 inches
Bacterial Filtration	99.9%	99.9%
Moisture Vapor Transmission Rate	1385 g/sqm/24hr	1385 g/sqm/24hr
Flammability	Class 1	Class 1
Synthetic Blood/ Viral Resistance	Pass	Pass

Sterility

The sterilization method is Ethylene Oxide (ETO). The method used to validate the sterilization cycle is overkill. The sterility assurance level (SAL) for the device will be 10^{-6} . The packaging for the sterile device is the same type as the predicate device.

The maximum levels of residues of ethylene oxide were less than 25 ppm, for ethylene chlorohydrin were less than 50 ppm and for ethylene glycol were less than 250 ppm from the sterilization process and are below allowable FDA limits.