

FEB 18 2000

K992445

510(k) Summary

a (1) Kappler USA, Inc.
PO Box 218
Guntersville, AL 35976

Contact: Philip Mann
(256) 505-4146

Prepared: August 18, 1999

a (2) Device Name: Surgical Gown
Proprietary Name: Med-Guard Surgical Gown
Classification Name: Gown, Surgical

a (3) This surgical gown is similar in design and composition to the Kimberly Clark gown identified in pre-market notification #K781682.

a (4) The Kappler Med-Guard surgical gown is constructed from a tri-layer composite material which is 100% polypropylene. The specific arrangement is spunbonded polypropylene/meltblown polypropylene film/spunbonded polypropylene. The fabric is treated with an anti-static agent.

a (5) The surgical gown is intended to protect the wearer from blood and other body fluids encountered during surgery.

a (6) The following table provides a comparison of the technological characteristics of the Kappler Med-Guard surgical gown and the Kimberly-Clark surgical gown. Description of the test methods are provided in section b.1. The K-C results were obtained from their own published literature.

CHARACTERISTIC	MED-GUARD	K-C
Material Composition	100% Polypropylene	100% Polypropylene
Configuration	Tri-laminate	Tri-Laminate
Barrier Layer	Meltblown	Meltblown
Composite Weight	1.8 oz./yd ²	1.5 oz./yd ²
Hydrostatic Head	44.0 cm	20.7 inches
Bacterial Filtration	78%	81.3%
Moisture Vapor Transmission Rate	1789 g/24 hm ²	1794 grs/sqm/24 hr
Flammability	Class 1	Class 1
Sterilization	100% ETO	100% ETO
Anti-static treatment	Yes	Yes

- b (1) The non-clinical testing was performed to describe the physical, barrier and comfort characteristics of the gown fabric. The individual test data sheets identify the samples as "Blue Hawk", which was a research and development name for the fabric in the Med-Guard gown.

Hydrostatic Pressure Resistance (ASTM D 751 Procedure B) - Provides a measure of the gown material resistance to a column of water. The results are expressed in the highest column resisted before failure occurs. See Enclosure A.

Bacterial Filtration Efficiency (SOP/ARO/007F.1/MIL-M-36954C) - Provides a measure of material resistance to bacteria laden aerosol with a mean particle size of approximately 3.0 microns. Results are expressed as a percentage of filtration. The test was performed on sterile material. See Enclosure B.

Moisture Vapor Transmission Rate (ASTM E 96 Method B) - Provides a measure of the gown material to pass water vapor and results are expressed in weight per unit area per unit time. Indicates a level of comfort for the wearer through ability to allow body perspiration to escape. See Enclosure C.

Standard Classification for Flammability (NFPA 702) - Provides a measure of the rate of burning of the gown material when ignited. Med-Guard shows the Class 1 flammability, which is defined as "relatively slow burning". See Enclosure D.

Ball Bursting Strength (ASTM D 751, Sec. 18.2) - Provides a measure of the physical strength of the gown material. Testing was performed on both sterile and non-sterile material to ensure sterilization would not adversely impact seam strength. See Enclosure E.

Breaking Strength (ASTM D 751, Sec. 11, Procedure A-Grab) - Provides a measure of the physical strength of the gown material. Testing was performed on both sterile and non-sterile material to ensure sterilization would not adversely impact physical strength. See Enclosure E.

Tear Strength (ASTM D 5733, Trapezoid Procedure) - Provides a measure of the physical strength of the gown material. See Enclosure E.

Colorfastness Evaluation of Non-wovens - Study consisted of performing water and saline extracts on the product after exposure to a normal steam cycle. See Enclosure E.

The product is 100% ETO sterilized. See Enclosure F.

- b (2) The clinical testing was performed to ensure the addition of the anti-static treatments presented no concerns of safety and effectiveness. The clinical protocol was established by North American Science Associates, Inc. (NAmsA). The protocol provided for the following testing:

Acute Systemic Toxicity - Hemolysis Test provides data to support no evidence of toxic effects from exposure to the treatment. See Enclosure G.

Cytotoxicity - MEM Emulsion is a measure of the cytotoxicity of extractable substances exposed to cellular monolayers. See Enclosure H.

Delayed Contact Sensitization Study - Provides data to show no evidence of irritation from exposure to the treatment. See Enclosure I.

Based on the results of the testing, NAmsA concluded that no concerns of safety or effectiveness resulted from the addition of the anti-static treatment.

- b (3) The results of the non-clinical and clinical tests show the Kappler Med-Guard gown to be safe and effective. The results also show the gown to be equivalent to the predicate device.

**FEB 18 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Philip C. Mann
Technical and Customer Support Manager
Kappler Protective Apparel & Fabrics
P.O. Box 218
Guntersville, Alabama 35976

Re: K992445
Trade Name: Med-Guard Surgical Gown
Regulatory Class: II
Product Code: FYA
Dated: January 24, 2000
Received: January 28, 2000

Dear Mr. Mann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

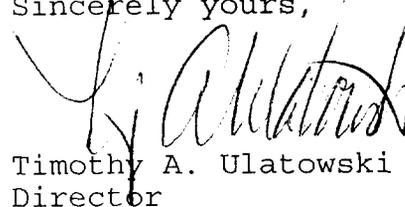
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992445

Device Name: MED-GUARD, Surgical Gown

Indications For Use:

The gown is intended to protect the patient & wearer from blood and other body fluids encountered during surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992445