

**International Medsurg Connection**

1000 E. Woodfield Road, Suite 117  
Schaumburg, IL 60173

Omi Bhati, M.D.  
President

JUN 24 1997

Ph (847) 517-6325  
Fax (847) 517-1447

K 971159

**I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

International Medsurg Connection  
1000 E. Woodfield Road, Suite 117  
Schaumburg, IL 60173  
Phone #: (847) 517-6325  
Fax #: (847) 517-1447  
Omi Bhati, M.D.  
President

Date Prepared: May 6, 1997

**Device Name**

Proprietary: N/A  
Common: Sterile O.R. Towels  
Classification Name: Surgical Drapes

**Product Description:**

Operating Room Towels are a 100% cotton woven towel. They are generally available in white (undyed), green or blue colors. O.R. Towels have been used throughout the Healthcare industry for a variety of purposes. These absorbent towels are utilized for hand drying, cleanup, and also for squaring off the surgical incision site, and to provide increased absorbency of blood and bodily fluids.

**Comparison to Legally Marketed Devices**

These O.R. Towels are similar to those already on the market as described below:

Medline Industries, Inc. Sterile OR Towels	A Plus International Sterile and Non-Sterile OR Towels	Ulti-Med International Absorbent Fiber Operating Room Towels
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**Technological Characteristics**

A. Similarities

The towels packaged and sold by International Medsurg Connection are substantially equivalent to those distributed by Medline Industries, Inc., A Plus International and Ulti-Med International. They are similar in weight, dimension, size, color, and thread count. All towels must be colorfast and must pass biocompatibility requirements. Since the towels are 100% cotton and the

biocompatibility of cotton as a medical product is well established, testing only was done to illustrate the biocompatibility of the dyed product. All three colors were tested and all three met the USP test requirements for cytotoxicity. In addition, testing for Primary Skin Irritation and Dermal Sensitization was conducted. Both test results were acceptable.

#### B. Differences

International Medsurg Connection towels differ from the predicate devices in that there may be minor differences in weight, absorbency, thread count, or size.

#### **Intended Use:**

For use in hospitals, clinics, laboratories or other facilities where absorbent toweling may be used.

For use as absorbent toweling for cleanup, preparation or squaring off a surgical incision site. For use during surgical procedures to provide extra absorption of blood and body fluids.

For use a) to dry off surgeons, doctor or nurses hands after scrubbing, (b) to square off a surgical incision site, and (c) to absorb blood or body fluids during a surgical procedure.

Not intended for use as surgical packing.

#### **Performance Data:**

These towels were tested for Tear Strength per ASTM D5034, Tensile Strength per ASTM D1424\*\* and Absorbency (USP). The results of this testing showed that the device was substantially equivalent to the current legally marketed devices.

\*\* Standard withdrawn by ASTM, January 1995



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 24 1997

Ms. Lara N. Simmons  
Corporate Regulatory Affairs Manager  
International Medsurg Connection  
1000 E. Woodfield Road, Suite 117  
Schaumburg, Illinois 60173

Re: K971159  
Trade Name: Surgical Drapes  
Regulatory Class: II  
Product Code: KKK  
Dated: May 6, 1997  
Received: May 7, 1997

Dear Ms. Simmons:

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.

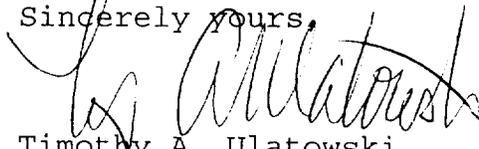
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Simmons

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) 594-4618. 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 at (301) 443-6597.

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): N/A K971159

Device Name: Sterile Operating Room Towels

Indications for Use:

For use in hospitals, clinics, laboratories or other facilities where absorbent toweling may be used.

For use as absorbent toweling for cleanup, preparation or squaring off a surgical incision site. For use during surgical procedures to provide extra absorption of blood and body fluids.

For use a) to dry off surgeons, doctor or nurses hands after scrubbing, (b) to square off a surgical incision site, and (c) to absorb blood or body fluids during a surgical procedure.

Not intended for use as surgical packing.

*Chin S. Kim*

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

(Division Sign-Off)

Division of Dental, Infection Control, and General Hospital Devices, Office of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K971159 OR

Over-The-Counter Use

Per 21 CFR 801.109

(Optional Format 1-2-96)