510(K) SUMMARY K100991

Trade Name:	IMC Surgical Drape
Common Name:	Surgical Drape
Classification Name:	Surgical Drape and Drape Accessories (21 CFR subpart E §878.4370)
Submitter Information:	International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173 OCT 5 2010
Summary Prepared By:	Peter Kim Quality Manager International Medsurg Connection 935 N Plum Grove Rd, STE F Schaumburg, Illinois 60173 Telephone: 847-619-9926 Fax: 847-619-9927 e-mail: peterkim@intlmedsurg.com
Date Prepared:	June 7, 2010
Predicate Devices:	• 3M Steri-Drape™ (K031287) • Medline (K003755)

Device Name(s):

IMC Surgical Drape

Classification Panel:

General and Plastic Surgery

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

International Medsurg Connections, Inc is claiming substantial equivalence of the IMC Surgical Drape with the currently marketed:

Description	510(k) Number	Clearance Date
3M Steri-Drape™	K031287	9/10/2003
Medline Blockade™ and Resistat™ Non-Sterile Surgical Gowns and Surgical Drapes	K003755	2/16/2001

Device Description

The IMC Surgical Drape devices are patient protective coverings used to isolate incision sites and protect against contamination during surgical procedures with the additional feature of a finger cot which is made of non-latex rubber.

The Bladder Suspension Drape, the GYN Drape and the TUR drape have the same features and same materials but have different dimension of drape and aperture.

Statement of Intended Use

These devices are intended to be used as protective coverings used to isolate incision sites and protect against contamination during surgical procedures with the additional feature of a finger cot which is latex-free rubber. This submission includes drapes that will be sold both sterile and non-sterile.

Non-sterile drapes are to be sold to OEMs for EO sterilization according to ANSI/AMMI/ISO 11135. Sterile drapes are to be sold directly to users after EO sterilization validation to ANSI/AMMI/ISO 11135

Catalog Number	Description
31-0051	Bladder Suspension Drape
31-0051NS	Bladder Suspension Drape
61-0091	GYN Drape
61-0091NS	G YN Drape
81-0011	TUR Drape
81-0011NS	TUR Drape

New Devices as Compared to Marketed Device(s)

The IMC Surgical Drape and the predicate devices (3M Steri Drape TM, and Medline Blockade™ and Resistat™ Non-Sterile Surgical Gowns and Surgical Drapes) to be used as protective coverings used to isolate incision sites and protect against contamination during surgical procedures with the additional feature of a finger cot.

Feature/ Characteristic	IMC Surgical Drape K100991	3M Steri-Drape™ K031287 (Predicate)	Medline K003755 (Predicate)
Material Composition			
Aperture for surgical site	These materials were tested in accordance with ISO 10993-5:2009, 10993-10:2002/Amd.1:2006, and 10993-11:2006(E) test methods and were found to be acceptable for the intended use	Similar	Similar
Absorbent Prevention Fabric	These materials were tested in accordance with ISO 10993-5:2009, 10993-10:2002/Amd.1:2006, and 10993-11:2006(E) test methods and were found to be	Same	Same

Feature/ Characteristic	IMC Surgical Drape K100991	3M Steri-Drape ™ K031287 (Predicate)	Medline K003755 (Predicate)
	acceptable for the intended use		
Finger Cot	These materials were tested in accordance with ISO 10993-5:2009, 10993-10:2002/Amd.1:2006, and 10993-11:2006(E) test methods and were found to be acceptable for the intended use	Same	same
Color Additive	These materials were tested in accordance with ISO 10993-5:2009, 10993-10:2002/Amd.1:2006, and 10993-11:2006(E) test methods and were found to be acceptable for the intended use	Same	Same
Design Feature			
Finger Cot	Bladder Suspension Drape, GYN Drape, TUR Drape	Same	Same
Fluid Collection Bag	Bladder Suspension Drape, GYN Drape, TUR Drape	Same	Same
Aperture			
Bladder Suspension	40cm (15.7") x 41cm (16.1")	Similar	Similar
GYN	25cm (9.8") x 25 cm (9.8")	Similar	Similar
TUR	12.5cm (4.9") x 7.5cm (2.95")	Similar	Similar

Performance Data:

Performance Characteristics	Test Method	IMC Surgical Drape K100991	3M Steri-Drape ™ K031287 (Predicate)	Medline K003755 (Predicate)
Flammability of Clothing Textiles Section 11	16 CFR Part 1610	Class I	Same	Same
Hydrostatic Pressure Section 12	AATCC 127-2008	Meets Intended use	Same	Same
Impact Penetration Section 13	AATCC 42-2007	Meets Intended use	Same	Same
Determine Lint and Other particles Section 14	ISO 9073-10	Meets Intended use	Same	Same
General Tensile Testing of Fabric Section 15	ASTM D5034-2009	Meets Intended use	Same	Same

Conclusions:

The indications for use, technology, specification, safety of the IMC Surgical Drapes and the two predicate devices K031287 and K003755 are essentially the same. The differences between the drapes are minor and do not raise new issues of safety or effectiveness. Hence, the IMC Surgical Drapes are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2010

International Medsurg Connection
C/O Mr. Peter Kim
935 N. Plum Grove Road, Suite F
Schaumberg, Illinois 60173

Re: K100991
Trade/Device Name: IMC Surgical Drape
Regulation Number: 21 CFR 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: September 16, 2010
Received: September 20, 2010

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100991

Device Name: IMC Surgical Drape

Indications for Use:

These devices are intended to be used as protective coverings used to isolate incision sites and protect against contamination during surgical procedures with the additional feature of a finger cot which is latex-free rubber. This submission includes drapes that will be sold both sterile and non-sterile.

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81-0011NS	TUR Procedure Drape

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Elizabeth F. Daniels-Wells

(Division Sign-Off)

Division Sign-Off Office of In Vitro Diagnostic Device Evaluation and Safety

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k)_____

510(k) Number: K100991