MAR 1 1 2005

K042893

10.0 SUMMARY OF THE SAFETY AND EFFECTIVENESS

International Medsurg Connection Fluid Collection Under Buttocks Drape

Manufacturer:	International Medsurg Connection, Inc. 935 N Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Regulatory Contact:	Teodoro Santiago TRS Consultant, Inc. P.O. Box 100624 Cudahy, WI 53110
Telephone:	414-861-2178
Date Summary Prepared	October 5, 2004
Product Trade Name:	Fluid Collection Under Buttocks Drape
Common Name:	Under Buttocks Drape.
Classification:	Class II
Predicate:	Under Buttocks Drapes, Reference K845112 owned by Kimberly Clark Corporation.
Description:	The International Medsurg Connection Fluid Collection Under Buttocks Drape.

Intended Use:
International Medsurg Connection's Fluid Collection Under Buttocks Drape is intended to be used as Fluid Collection and by placing under a patient's buttocks in obstetrics procedure (with absorbent pad).

Substantial Equivalence:
The International Medsurg Connection Fluid Collection Under Buttocks Drapes are substantially equivalent to the Kimberly Clark Fluid Collection Under Buttocks Drape (catalog number 89414) sold by Kimberly Clark, Reference K842115.

Summary of testing:

International Medsurg Connection Fluid Collection Under Buttocks Drape were tested for:

Test	Standard
Cytotoxicity	ISO 10993-Part 5
Skin Sensitivity	ISO 10993 – Part 10
Skin Irritation	ISO 10993 – Part 10
Systemic Toxicity	ISO 10993 – Part 11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2005

International Medsurg Connection, Incorporated
C/O Mr. Teodoro Santiago
Regulatory Consultant
Total Regulatory Systems Consultant, Incorporated
P.O. Box 100624
Cudahy, Wisconsin 53110

Re: K042893
Trade/Device Name: International Nedsurg Connection's Fluid Collection Under Buttocks Drape
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: KKX
Dated: February 22, 2005
Received: February 24, 2005

Dear Mr. Santiago:

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.

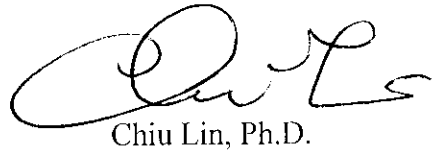
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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

510K Number : K042893

Device name: International Medsurg Connection's Fluid Collection Under Buttocks Drape

Indication For Use:

International Medsurg Connection's Fluid Collection Under Buttocks Drape is intended to be used in obstetric procedure to collect fluid and by placing under a patient's buttocks (with absorbent pad).

Prescription Use__X_____ AND/OR Over-The counter Use_____
(Partb21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of anesthesiology, General Hospital.
Infection Control Dental Devices