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K023808

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

INTERNATIONAL MEDSURG CONNECTIONS IRRIGATION SETS

Manufacturer:	International Medsurg Connections, Inc. 935 N. Plum Grove Road, Suite F Schaumburg, Illinois 60173-4770
Regulatory Affairs Contact:	Michele Vovolka P.O. Box 848 Grayslake, Illinois 60030
Telephone:	(847) 856-0355
Date Summary Prepared:	November 5, 2002
Product Trade Name:	TUR, Arthroscopic, Cystoscopy Irrigation Sets
Common Name:	Irrigation Sets
Classification:	Class II

Predicate Devices:

Description: The International Medsurg Connections Irrigation Sets.

Intended Use:
This device is intended for delivery of irrigation solutions from the fluid container to the irrigation site during bladder irrigation or endoscopic procedures including cyctoscopy, transurethral resection (TUR) and arthroscopic procedures. This tubing segment is connected to the endoscope for delivery of solution to the irrigation site such as the bladder or knee.

Substantial Equivalence:
The International Medsurg Connections Irrigation Sets are substantially equivalent to the Baxter Healthcare Corporation Irrigation Sets in that they provide the following characteristics:

- Intended use is the same
- Similar configurations
- Similar materials

Summary of Testing: All materials used in the fabrication of the International Medsurg Connections Irrigation Sets were evaluated for:

Joined Tubing 5" and 20"	**Irrigation Sets***
Oxidizable Matter	Oxidizable Matter
Acidity and Alkalinity	Acidity and Alkalinity
UV Absorbancy	UV Absorbancy
Metallic ions	Metallic ions
Evaporated Residual	Evaporated Residual
Diameter of the end conical fitting	Integrity
Length of conical fitting	Connection between components
Taper of conical fitting	Closure-piecing device
Separate force of conical fitting	Tubing
Tightness of conical fitting	Drip chamber and drip tubing
Force of split the conical fitting	Flow rate of infusion
Diamter of conical aperature	Flow regulator
Depth of conical aperature	Self-sealing injection site
Taper of conical aperature	Protective caps
Separate force of conical aperature	Symbol
Tightness of conical aperature	Packing
Force of split the conical aperature	Chemical property
Outer diameter of conical fitting on outstanding position	
Angle of conical fitting on outstanding postion	
Length of tubing	
Connection Strength	
Integrity	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

International Medsurg Connection
% Ms. Michele H. Vovolka
Regulatory Consultant
Vantage Consulting International, Ltd.
P.O. Box 848
GRAYSLAKE IL 60030

Re: K023808
Trade/Device Name: Irrigation Sets
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LJH
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: 87 HRX
Dated: February 18, 2003
Received: February 19, 2003

Dear Ms. Vovolka:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K023808

Device Name: International Medsurg Connections Irrigation Sets

Indications For Use:

This device is intended for delivery of irrigation solutions from the fluid container to the irrigation site during bladder irrigation or endoscopic procedures including cyctoscopy, transurethral resection (TUR) and arthroscopic procedures. This tubing segment is connected to the endoscope for delivery of solution to the irrigation site such as the bladder or knee.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** _____ **Over -The-Counter Use**
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023808

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