K014239 **Attachment D**

510(k) Summary FEB 1 9 2002

INTERNATIONAL MEDSURG CONNECTIONS EQUIPMENT COVERS

Manufacturer:	International Medsurg Connections, Inc. 1000 E. Woodfield Road, Suite 102 Schaumburg, Illinois 60173-5921
Regulatory Affairs Contact:	Michele Vovolka P.O. Box 848 Grayslake, Illinois 60030
Telephone:	(847) 856-0355
Date Summary Prepared:	December 17, 2001
Product Trade Name:	International Medsurg Connections Equipment Covers
Common Name:	Equipment Covers
Classification:	Non-classified

Predicate Devices:

Cover-All, Drape-It-All - Pinnacle Products, Inc. - K962288
Equipment Covers - United States Surgical - K961699
Sterile Equipment Covers - Custom Medical Products, Ltd. - K931417

Description: The International Medsurg Connections equipment covers are made of polyethylene. The covers are offered sterile and non-sterile.

Intended Use: These equipment covers are equipment drapes or drape accessories made of natural or synthetic materials intended to be used as a protective patient covering such as to isolate a site of surgical incision from microbial and other contamination.

Substantial Equivalence:
The International Medsurg Connections Equipment Covers are substantially equivalent to the Pinnacle Products, United States Surgical, and Custom Medical Product equipment covers in that they provide the following characteristics:

- Intended use is the same
- Size, configuration, color are similar
- Made of polyethylene
- Physical properties are similar

Attachment D

510(k) Summary

Summary of Testing:

The following tests were performed on the finished Medsurg equipment covers:

Test Method	Standard Used
Flammability Testing, Class 1	16 CFR 1610
Hyrostatic Pressure Test – Fluid Penetration Test	AATCC Test Method 127-1989
Grab Tensile	ASTM D882-91
Tear Resistance – Strip Tensile	ASTM D1424-96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 9 2002

International MedSurg Connection
Regulatory Consultant
C/O Ms. Michele H. Vovolka
Vantage Consulting International Limited
P.O. Box 848
Grayslake, Illinois 60030

Re: K014239
Trade/Device Name: International Medsurg Connections Equipment Covers
Regulation Number: 878.4370
Regulation Name: Equipment Covers
Regulatory Class: Unclassified and II
Product Code: MMP and KXX
Dated: December 17, 2001
Received: December 26, 2001

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 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 and additionally 21 CFR Part 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" (21CFR 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,

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

Enclosure

Attachment E

510(k) Number (if known): K014239

Device Name: International Medsurg Connections Equipment Covers

Indications For Use:

These equipment covers are equipment drapes or drape accessories made of natural or synthetic materials intended to be used as a protective patient covering such as to isolate a site of surgical incision from microbial and other contamination.

(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)

(Division Sign-Off)
Division of Dental, Infection Control,
And General Hospital Devices

510(k) Number K014239