K022159

Attachment 3

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

INTERNATIONAL MEDSURG CONNECTIONS SYRINGE AND NEEDLES NOV 7 2002

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:	October 11, 2002
Product Trade Name:	International Medsurg Connections Equipment Covers
Common Name:	Piston Syringe and Needles
Classification:	Class II

Predicate Devices:

Description:	The International Medsurg Connections piston syringe and hypodermic needle. The covers are offered sterile, single use.
Intended Use:	This device is intended for inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe consisting of a calibrated hollow barrel and a movable plunger

Substantial Equivalence:
The International Medsurg Connections piston syringe and hypodermic needles are substantially equivalent to the Becton Dickinson Piston Syringes and the Nipro needles in that they provide the following characteristics:

- Intended use is the same
- Size, configuration, color are similar
- Materials
- Physical properties are similar

Attachment 3

Summary of Testing: All materials used in the fabrication of the International Medsurg Connections O.R. piston syringe and hypodermic needles were evaluated for:

Testing Items	**Code Requirement**
Syringe Column Sealing	300 Kpa Positive Pressure – No leakage 88 Kpa Negative Pressure – No leakage
Volume	± 4%
Tip Sealing Property	No Leakage
Indicating Ruler – 0 level line	Within ¼ range
Tip size, Draw Strength	No separation at 25N
Residue Contents	< 0.075 mL
Sliding Property	Average <10N
Appearance	Clean, Smooth
Non-Bacteria	Non-Bacteria
Pyrogen	Pyrogen-Free
Toxicity	Non-toxic, no toxicity reaction for human body

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

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

Re: K022159
Trade/Device Name: International Medsurg Connections Syringe and Needles
Regulation Number: 880.5860 and 880.5570
Regulation Name: Piston Syringe and Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMF and FMI
Dated: October 11, 2002
Received: October 15, 2002

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.

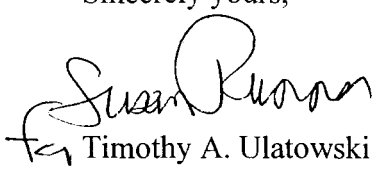
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

Attachment 4

510(k) Number (if known): K022159

Device Name: International Medsurg Connections Syringe and Needles

Indications For Use:

This device is intended for inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin. The device consists of a metal tube that is sharpened at one end and at the other end joined to a female connector (hub) designed to mate with a male connector (nozzle) of a piston syringe consisting of a calibrated hollow barrel and a movable plunger.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cicenia

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

510(k) Number: K022159

(Optional Format 3/10/98)