K972117

AUG 26 1997

Attachment 1
510(k) Summary

Medical Specialty Innovations, Inc.
Transfer Devices

Submitter Information:

Medical Specialty Innovations, Inc. (MSI)
440 Nine McFarland Drive, Suite 100
Alpharetta, GA. 30201

510(k) Summary Prepared by:

Carolann Kotula
Official Correspondent for MSI
c/o mdi Consultants, Inc.
55 Northern Boulevard
Great Neck, NY 11021

Phone: (516) 482-9001
Fax: (516) 482-0186

Date 510(k) Summary Prepared: May 30 , 1997

Name/Classification of the Device:

Classification Name: IV Container Accessories

Common Name: Transfer device: bottle or bag decanter, transfer spike

Proprietary Name: MSI Bottleflow, Transflow, Vialflow and Rapidflow

Classification: These have been classified by the General Hospital Panel as Class II devices.

Identification of the Legally Marketed Device to which the Submitter Claims Equivalence: These devices are substantially equivalent to the transfer devices legally marketed by MediPlast International, Inc. as:

IV Plastic Bag decanter:	K811233
IV Rigid (Bottle) decanter:	K811234
Bottle to Bottle decanter:	K811268
Glass Vial decanter:	K811269

Comparative Information: The subject device and predicate are substantially identical in materials,dimensions, performance, packaging, sterilization and intended use.

Description of the Subject Device: The MSI transfer devices are one piece, injection molded transparent hollow tubes with one or more spiked ends. Some models have a splash guard. They are sterile, disposible devices.

Intended Use of the Subject Device: The MSI transfer devices are decanting devices intended for the asceptic dispensing of solutions from IV containers. Each device is used as follows

VialFlow:	used to dispense fluids from glass vials
RapidFlow:	used to dispense fluids from flexible bags
BottleFlow:	used to dispense fluids from Large Glass IV Bottles
TransFlow:	used to dispense fluids from small vial, or to transfer solutions from container to container

Technological Characteristics of the Subject Device: There are no differences in the characteristics of the subject devices and the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 1997

Ms. Carolann Kotula
Vice President
Medical Specialty Innovations, Incorporated (MSI)
C/O MDI Consultants, Incorporated
55 Northern Boulevard
Great Neck, New York 11021

Re: K972117
Trade Name: MSI Bottleflow, Transflow, Vialflow
Regulatory Class: II
Product Code: LHI
Dated: May 30, 1997
Received: June 5, 1997

Dear Ms. Kotula:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

K972117

ATTACHMENT #3

510(k) Number (if known) _____

Device Name: Medical Specialty Innovations, Inc. Transfer Devices

Indications for Use:

The MSI transfer devices are decanting devices intended for the aseptic dispensing of solutions from IV containers. Each device is used as follows

VialFlow: used to dispense fluids from glass vials
RapidFlow: used to dispense fluids from flexible bags
BottleFlow: used to dispense fluids from Large Glass IV Bottles
TransFlow: used to dispense fluids from small vial, or to transfer solutions from container to container

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Adrienne Cicconetti
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972117

Prescription Use ✓ OR Over the Counter Use _____