AUG 24 1998

K982587

510(k) Summary

1. Submitter: **Medical Product Specialists, Inc.** (MPS)
499 Nibus Street, suite E
Brea, CA 92821
Tel: 714-257-0470
Fax: 714-257-0513

2. Contact: Dan Hyun, President
Medical Products Specialists

3. Date prepared: June 29, 1998

4. Device trade name: MPS Fixed Flow Rate Set

Common name: Intravenous (I.V.) Sets Accessory

5. Predicate device: I-Flow® Fixed Flow Rate Gravity Set
Manufactured by I-Flow Corp., Irvine CA 92714

6. Description: The MPS Fixed Flow Rate Set is a family of specialized IV sets designed to deliver a fluid flow at a specified rate. The MPS Fixed Flow Rate Set incorporates a standard bag spike, flexible drip chamber, microbore infusion tubing, and ending with a standard male luer connector with luer-lock. Flow rate control is established by the flow dynamics of the microbore infusion tubing. Each set is provided with a spike protector, luer cap, and tubing clamp. Various configurations may also include 0.2 micron IV filter.

Each MPS Fixed Flow Rate Set is sterilized in sealed individual pouches or trays. Full labeling information is provided with each MPS Fixed Flow Rate Set . Multi-unit shelf packs of individual pouches or trays are provided for convenience.

7. Intended Use:

1. The MPS Fixed Flow Rate Set is intended for single use in continuous or intermittent infusion therapy.

2. For use for infusion of I.V. fluids, and drugs.

8. Technological comparison to predicate device:

The technological characteristics are intended to be substantially equivalent (in materials, design, and intended use) to the devices currently marketed as the I-Flow Fixed Flow Rate Gravity Set.

There are no technological differences between the I-Flow Fixed Rate Gravity Set and the MPS Fixed Flow Rate Set. Both devices control gravity flow rates by varying the length of fixed internal diameter microbore tubing.

9. Nonclinical test summary:

Plastic component materials and bonding agents have been tested per ISO 10993 Biological Testing of Medical and Dental Materials. Testing indicates that materials are safe and biocompatible.

10. Conclusion: The MPS Fixed Flow Rate Set is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 24 1998

Mr. Dan Hyun
President
Medical Product Specialists, Incorporated
499 Nibus Street, Suite E
Brea, California 92821

Re: K982587
Trade Name: MPS Fixed Flow Rate Set
Regulatory Class: II
Product Code: FPA
Dated: June 29, 1998
Received: July 24, 1998

Dear Mr. Hyun:

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 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). 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 requirements, 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) 594-4692. 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"(21CFR 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/dsma/dsmamain.html".

Sincerely yours,

S. Dutmer for

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

Enclosure

K 982587

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

(As required by ODE for all 510(k) received after Jan. 1, 1996.)

510(k) Number: K982587

Device Name: MPS Fixed Flow Rate Set

Indications For Use:

1. The MPS Fixed Flow Rate Set is intended for single use in continuous or intermittent infusion therapy.

2. For use for infusion of I.V. fluids and drugs.

(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)

Nicole Hubbard for Pat Cricenti
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982587