K983926

JAN 20 1999

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:	November 2, 1998
4.	Device trade name:	MPS Gravity Flow Control Set
	Common name:	Intravenous (I.V.) Sets Accessory
5.	Predicate device:	Master Medical Corporation Marketed by ConMed Corp. 310 Broad St. Utica, NY 13051 K871753 and K852254
6.	Description:	The MPS Gravity Flow Control Set is a family of specialized IV sets designed to deliver a fluid flow at a specified rate. The MPS Gravity Flow Control Sets will be available in both primary I.V. sets and extension sets. It incorporates a standard bag spike, flexible drip chamber, PVC tubing, Clamp and ending with a standard male luer lock. Various flow rates are established by rotating the barrel to vary the position of the accurate slot in the barrel relative to the oppositely disbursed inlet and outlet. Each MPS Gravity Flow Control Set is sterilized in sealed individual pouches or trays. Full labeling information is provided with each MPS Gravity Flow Control Set . Multi-unit shelf packs of individual pouches or trays are provided for convenience.
7.	Intended Use:	
	1.	The MPS Gravity Flow Control Set is intended only for a gravity infusion of I.V. fluids and drugs.
	2.	The MPS Gravity Flow Control Set incorporates a rotary device to set and maintain a pre-selected flow rate for I.V. fluids and drugs to a patient.
	3	The MPS Gravity Flow Control Set is intended for single use in the I.V. infusion. Change per CDC guidelines or per hospital protocol.

4. Do not use the MPS Gravity Flow Control set with a pressure infusion device.

5. Do not administer blood, blood product or enteral solution.

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 ConMed Corporation STAT-2 (original 510(k) was issued to Master Medical Corp.)

There are no technological differences between the Master Medical STAT-2 set and the MPS Gravity Flow Control Set. Both devices control gravity flow rates by rotating the barrel to vary the position of the accurate slot in the barrel relative to the oppositely disbursed inlet and outlet.

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 Gravity Flow Control 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

JAN 20 1999

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

Re: K983926
Trade Name: MPS Gravity Flow Control Set
Regulatory Class: II
Product Code: FPA
Dated: November 2, 1998
Received: November 5, 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,

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

Enclosure

K983926

REVISED

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

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

510(k) Number: K983926

Device Name: MPS Gravity Flow Control Set

Indications For Use:

1. The MPS Gravity Flow Control Set is intended only for a gravity infusion of I.V. fluids and drugs.

2. The MPS Gravity Flow Control Set maintains a pre-selected flow rate for I.V. fluids and drugs to a patient.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) C. Benkert
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983926

prescription Use ✓ or over-the-counter Use ____
(Per 21 CFR 801.109)