K982048

JUL 27 1998

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: May 29, 1998

4. Device trade name: MPS Reservoir Bag

   Common name: I.V. container (21 CFR § 880.5025)
   Drug bag
   Drug reservoir

5. Predicate device: Baxter Drug Bag

6. Description: Each MPS Reservoir Bag is sterilized in sealed individual pouches. Full labeling information is provided with each MPS Reservoir Bag. Multi-unit shelf packs of individual pouches or trays are provided for convenience.

7. Intended Use:
   1. The MPS Reservoir Bag is intended for use with Ambulatory PCA or APII pumps for continuous infusion therapy.
   2. For use for infusion of I.V. fluids, and drugs. Refer to the directions for use of the infusion pump for compatible indications for use.
   3. For use up to 24 hours per CDC guidelines or per hospital protocol.
   4. For use with standard luer taper connections.
   5. For single patient use.

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 Baxter Drug Bag.

Difference between the proposed and predicate devices are in the color coding scheme for vented and non-vented luer caps. And that the slide clamp is attached to the bag in the MPS Reservoir Bag design where the clamp is enclosed in the interior sterile pouch in the Baxter design.

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 Reservoir Bag 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

JUL 27 1998

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

Re: K982048
Trade Name: MPS Reservoir Bag
Regulatory Class: II
Product Code: KPE
Dated: May 29, 1998
Received: June 10, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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,

Patricia Cricenti 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

K982047

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

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

510(k) Number:

Device Name: MPS Huber Needle Extension Set

Indications For Use:

a. The MPS Huber Needle Extension Set is intended for use with implanted infusion ports for continuous or intermittent infusion therapy.

b. For use for infusion of I.V. fluids, blood, blood products and drugs.

c. Change per CDC guidelines or per hospital Protocol.

(Do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K982047

Prescription Use ✓
(Per 21 CFR 801.109)

or

Over-The-Counter Use _____