

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 Product Specialists
3. **Date prepared:** May 29, 1998
4. **Device trade name:** MPS Huber Needle Extension Set
Common name: Intravenous (IV) Medication Connector and IV Sets
Implanted infusion port needle
Huber needle
5. **Predicate device:** GISH VASTACK®
6. **Description:** The MPS Huber Needle Extension Set is a family of sterile and non-pyrogenic devices used for transdermal infusion via subcutaneous access ports. These devices consist of angled non-coring stainless steel needle bonded to microbore infusion tubing ending with a standard female luer connector with luer-lock. Each set is provided with a needle tip protector, luer cap, and color coded stabilization wings. Various configurations may also include Y injection sites, and clamps typically associated with standard microbore tubing infusion sets.

Each MPS Huber Needle Extension Set is sterilized in sealed individual pouches or trays. Full labeling information is provided with each MPS Huber Needle Extension Set. Multi-unit shelf packs of individual pouches or trays are provided for convenience.
7. **Intended 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.

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 under the trade name Gish VASTACK®.

The design variation is in the needle grip. The Gish VASTACK design is a clear rigid grip with a foam pad for patient comfort. The proposed MPS Huber Needle Extension Set grip incorporates the flexible color coded wings typically present on infusion needle sets, with a raised pattern on the patient contact surface for comfort. This design difference is not expected to effect safety nor effectiveness of the MPS Huber Needle Extension Set in its intended use.

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. Component metals shall meet an ASTM standard where biocompatibility is indicated.

10. Conclusion:

The MPS Huber Needle Extension Set is substantially equivalent to the legally marketed predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1998

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

Re: K982047
Trade Name: MPS Huber Needle Extension Set
Regulatory Class: II
Product Code: FPA
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,

A. Dutman 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 982047

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)

Palacio Cucenta

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

510(k) Number 1982047

Prescription Use
(Per 21 CFR 801.109)

or

Over-The-Counter Use