K983034

MEDICAL INFUSION TECHNOLOGY, INC.

PREPARE™ HOME INFUSION PUMP

510(k) SUMMARY

Submitter Name:	Medical Infusion Technology, Inc.
Submitter's Address:	6576 E. Quaker Street Orchard Park, NY 14127
Contact Person:	John Wynne, President
Phone Number:	716-667-3318
Facsimile Number:	716-667-3319
Date Prepared:	October 9, 1998
Device Trade Name:	Prepare™ Home Infusion Pump
Device Common Name:	Elastomeric Infusion Pump
Classification Name:	Infusion Pump, 21 CFR 880.5725
Predicate Device:	Homepump, Block Medical, Inc.
Device Description:	An infusion pump used to pump fluids into a patient in a controlled manner.
Intended Use:	Provide controlled, continuous, intravenous fluid therapy for ambulatory patients.
Technological Characteristics and Comparison to Predicate Device(s).	Both the Block Medical Homepump and the Prepare™ Home Infusion Pump are equivalent in design, material, intended use and function.
Performance Data:	The Prepare™ Home Infusion Pump has been functionally tested to confirm documented performance which demonstrates substantial equivalence to the predicate device.
Conclusion:	The Prepare™ Home Infusion Pump is safe and effective for its intended use and meets all regulatory requirements to be found substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 24 1999

Mr. Thomas L. Parker
Medical Infusion Technologies, Incorporated
6576 East Quaker Street
Orchard Park, New York 14127-2593

Re: K983634
Trade Name: Prepare Home Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: February 5, 1999
Received: February 8, 1999

Dear Mr. Parker

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,

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

Enclosure

SECTION 5

INDICATIONS FOR USE

PREPARE™ HOME INFUSION PUMP

"Provide controlled, continuous, intravenous fluid therapy for ambulatory patients."

Prescription Use ✓
21 CFR 801.109

(Division Sign-Off)
General Hospital and General Use Devices

510(k) Number _____

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

510(k) Number K983634