JUN 21 2000

K001629

9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY"

9.1 Trade/Proprietary Name: Disetronic Multifuse Infusion Pump System

9.2 Common/Usual Name: Peristaltic Infusion Pump and Accessories

9.3 Classification Name: Infusion Pump/Intravascular Administration Set

9.4 Comparison to Currently Marketed Devices

The Disetronic Multifuse Infusion Pump is substantially equivalent to the currently marketed Disetronic Multifuse Infusion Pump (K990259).

9.5 Device Description

The Disetronic Multifuse pump is a small, battery-operated peristaltic infusion pump that is suited for ambulatory hospital and home use. The pump is extremely versatile. It has been designed to allow the health provider program the pump to provide one of several types of infusion therapies. The pump can be configured as a continuous rate infusion pump with demand bolus capability, a variable rate infusion pump with demand bolus capability, a Patient Controlled Analgesia (PCA) pump, a Total Parenteral Nutrition (TPN) pump or an intermittent infusion pump. The health provider can further customize the pump for a specific patient by allowing or excluding optional programming steps, limiting allowable ranges, adjusting the rate at which boluses are infused and adjusting alarm and display features.

9.6 Indications for Use

The modified Disetronic Multifuse Pump with its accessories has the same indications and intended use as the currently marketed device.

9.7 Testing

The Disetronic Multifuse Infusion Pump has been designed and tested in accordance with IEC 601-2-24 and associated standards.

9.8 Software

Disetronic has adhered to all software development procedures and Good Quality Assurance procedures. All test results demonstrate that the system specifications and functional requirements were met.

9.9 Conclusion

Based on the functional comparison, design equivalency and the functional and safety testing, Disetronic has determined that the Multifuse Infusion Pump and accessories are substantially equivalent to the currently marketed device in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 21 2000

Disentronic Medical System AG
C/O Mr. Lee Leichter
P/L Biomedical
7690 Cameron Circle
Fort Myers, Florida 33912

Re: K001629
Trade Name: Disetronic Multifuse Infusion Pump System
Regulatory Class: II
Product Code: FRN
Dated: May 26, 2000
Received: May 26, 2000

Dear Mr. Leichter:

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

INDICATIONS FOR USE STATEMENT

510(k) File Number: ~~K00016~~ WMR K001629

Device Name: Multifuse Infusion Pump

Indications For Use: The Disetronic Multifuse Infusion Pump, with its accessories, is indicated for the controlled delivery of parenteral fluids, including patient controlled analgesia (PCA), in both the hospital and home care environments.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cruente
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001629

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.19)