DEC 30 1999

510(K) SUMMARY

K994186

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: Disetronic D-TRON Insulin Infusion Pump

9.2 Common/Usual Name: Insulin Infusion Pump and Accessories

9.3 Classification Name: Infusion Pump

9.4 Substantial Equivalence: The Disetronic D-TRON Insulin Infusion Pump is substantially equivalent to the Disetronic H-TRON Plus V100 Insulin Infusion Pump (K973044).

9.5 Device Description

The Disetronic D-TRON Insulin Infusion Pump is an ambulatory, battery operated pump that administers small quantities of insulin to the patient. It is compact, watertight and shock resistant to maximize patient convenience. The total system consists of the pump and custom reservoir kit. The pump is compatible with commercially available subcutaneous administration sets with standard female luer connectors. The labeling provided in the appendices contain detailed pictorial representations, descriptions and instructions that are adequate to facilitate evaluation of the nature and operation of the device.

Insulin delivery is accomplished through the reservoir piston mechanism. The piston is advanced by means of a stepper motor driving a rubber piston forward into the cartridge. The frequency of the motor revolution is controlled by the microprocessor according to the information programmed by the user or their care provider. The rate of the basal infusion each hour for twenty-four hours, subsequent boluses and any temporary increase or reduction in the basal rate can be simply entered using the four buttons on the pump. Additionally, the user controls infusion start, infusion stop and has access to information important to proper monitoring of the pump and the therapy.

Two separate 24-hour profiles for the delivery of insulin can be programmed independently for each hour of the day. The hourly dose can be incremented to a maximum of 25 I.U. per hour. The basal delivery can be supplemented by a bolus up to 25 I.U.

Four push buttons on the pump let the patient manage the pump's functions and access current and historical information. The data entered or information accessed is displayed on a Liquid Crystal Display (LCD) and all actions are audibly confirmed. For safety and convenience, the user enters data in insulin units, eliminating the need to convert units to volume.

The pump is designed with a comprehensive set of safety systems, alarms and alerts. When the pump senses any of the specified conditions it notifies the user with an intermittent beep (and/or vibration) and a visual display of the fault. The audible alarm can be canceled by pressing a button acknowledgment of the fault condition. The indication remains on the LCD until the fault is eliminated.

The pump housing is made of impact resistant plastic. All screw connections and buttons are sealed making the pump watertight per IEC standards.

9.6 Intended Use
The Indications for use and intended use have not changed.

9.7 Technological Characteristics
The technological characteristics of the device have not been affected by these modifications.

9.8 Performance Data
The Disetronic D-TRON Insulin Infusion Pump has been designed in accordance with IEC 60601-2-24 of the International Electrotechnical Commission First Edition 1998-02: Particular requirements for safety of infusion pumps and controllers. IEC 60601-2-24 incorporates the requirements of IEC 60601-1 for all general safety requirements and 60601-1-2 for Electromagnetic Compatibility - Requirements and Tests.

The electronic and mechanical design is not unique and therefore the specifications fully address pump performance. Disetronic has adhered to all software development procedures and Good Quality Assurance procedures.

9.9 Conclusion
Based on the functional comparison, design equivalency and the functional and safety testing, Disetronic has determined that the D-TRON Insulin Infusion Pump is substantially equivalent to the un-modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 30 1999

Mr. David E. Chadwick, Ph.D.
Director, Regulatory Affairs
Disetronic Medical Systems, Inc.
5151 Program Avenue
St. Paul, Minnesota 55112-1014

Re: K994186
Trade Name: Disetronic H-TRON Plus Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: December 6, 1999
Received: December 10, 1999

Dear Mr. Chadwick:

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,

Gerald W Shipley

Timothy A. Ulatowski for
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: K994186

Device Name: Disetronic D-TRON Insulin Infusion Pump

Indications For Use: The Disetronic D-TRON Insulin Infusion Pump is intended for the controlled delivery of insulin as prescribed by a physician.

It is indicated for patients with insulin dependent diabetes Mellitus who do not have optimum blood glucose control on conventional insulin injection therapy. Patients for insulin pump therapy must be highly motivated to perform self glucose monitoring on a frequent and regular basis, as well as adhere to a proper diet and exercise regiment. Patients must be capable of operating the pump. They must also have access to the educational training, support, and follow-up of health care professional experienced in insulin pump therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Mark Hibbard for Pat Cricenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994186