K973044

SEP 15 1997

510(K) SUMMARY

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: Disetronic H-TRON Plus 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 H-TRON Plus V 100 Insulin Infusion Pump is substantially equivalent to the Disetronic H-TRON V 100 Insulin Infusion Pump (K905693).

9.5 Device Description
The physical dimensions and specifications, pumping method, safety systems, accuracy and basic design and operation of the device have not been changed by the modifications.

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 H-TRON Plus V 100 Insulin Infusion Pump has been designed and tested in accordance with IEC 601-2-24 of the International Electrotechnical Commission Technical Committee No. 62: Electrical Equipment in Medical Practice Sub-Committee 62D: Electromedical Equipment - Draft Date: August 29, 1994 - Part 2: Particular requirements for safety of infusion pumps and controllers. IEC 601-2-24 incorporates the requirements of IEC 601-1 for all general safety requirements including IEC 801-2 and 801-3 for Electromagnetic Interference (EMI)) and Electrostatic Discharge (ESD).

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. 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 H-TRON Plus V 100 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

SEP 15 1997

Mr. Jim Myers
Vice President
Disetronic Medical Systems
5201 East River Road, #312
Minneapolis, Minnesota 55421-1014

Re: K973044
Trade Name: Disetronic H-Tron Plus V 100 Insulin Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: August 12, 1997
Received: August 15, 1997

Dear Mr. Myers:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. 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), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. 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 at (301) 443-6597.

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

Enclosures

INDICATIONS FOR USE

510(k) File Number:

Device Name: Disetronic H-Tron Plus V 100 Insulin Infusion Pump

Indications For Use: The Disetronic H-TRON V 100 Plus 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.

Patricia Cucinotta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973044