

JUN 15 1999

510(K) SUMMARY

K991376

9.0 Summary of Safety and Effectiveness

9.1 Trade/Proprietary Name: DAHEDI Insulin Infusion Pump

9.2 Common/Usual Name: Insulin Infusion Pump and Accessories

9.3 Classification Name: Infusion Pump

9.4 Substantial Equivalence: The DAHEDI Insulin Infusion Pumps are substantially equivalent to the Disetronic H-Tron Plus V 100 Insulin Infusion Pumps (K973044).

9.5 Device Description

The DAHEDI Insulin Infusion Pump is a very small, ambulatory, battery operated portable pump that is designed for the treatment of Insulin Dependent Diabetes Mellitus. The DAHEDI Insulin Infusion Pump infuses small amounts of insulin through a catheter into the patient via subcutaneous administration twenty-four hours a day. It is compact, watertight and shock resistant to maximize patient convenience. 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.

The pump uses a commercially available insulin reservoir that holds regular insulin into which the pump drives a piston rod that displaces precise amounts of insulin at exact times throughout the day. Insulin is delivered from the insulin reservoir of the pump to the body through a thin, plastic tube called an "infusion set." The infusion set has a small needle or flexible catheter that the user inserts under the skin (most commonly in the subcutaneous tissue of the abdomen). Insulin passes through the infusion set into a needle or a soft Teflon cannula into the body. The pump is compatible with all commercially available subcutaneous insulin infusion sets with female luer lock connectors.

The insulin reservoirs and catheters are sterile and single use (disposable). The pump itself is not sterile as it does not come in contact with the insulin.

Insulin delivery is accomplished through the reservoir piston mechanism. The piston is advanced by means of a motor driving a piston forward into the cartridge. The frequency of the motor revolution is controlled by the pump according to the information entered into the pump by the user or his care provider. The rate of the basal infusion, initiation of boluses, any dosage limitations or modifications can be simply entered using the buttons on the pump. Additionally, the user controls infusion start, infusion stop and has access to information important to the proper monitoring of the pump and the therapy. An optional IR adapter allows the user to send 42 days of history into a standard IBM compatible Personal computer.

9.6 Intended Use

The Indications for use and intended use are the same as those for the predicate device.

9.0 Summary of Safety and Effectiveness Continued

9.7 Technological Characteristics

The DAHEDI Insulin Infusion Pump incorporates a proprietary digital control chip that has been hardwired to operate all functional and safety control parameters. This function has been accomplished by software resident in a microprocessor in other equivalent devices. All other functional and technological characteristics are similar to the predicate device.

9.8 Performance Data

The DAHEDI 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 - 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 601-1-2 Electromagnetic Interference (EMI).

Disetronic has adhered to Good Design, Manufacturing and Quality Assurance procedures. All test results demonstrate that the system specifications and functional requirements were met.

9.9 Conclusion

Based on the functional comparison and the performance and safety testing, Disetronic has determined that the DAHEDI Insulin Infusion Pump is substantially equivalent to the Disetronic H-TRON Plus V 100 Insulin Infusion Pump.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 15 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Disetronic Medical Systems, Incorporated
c/o Lee Leichter
P/L Biomedical
7690 Cameron Circle
Fort Meyers, Florida 33912

Re: K991376
Trade Name: DAHEDI Insulin Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: April 21, 1999
Received: April 21, 1999

Dear Lee 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.

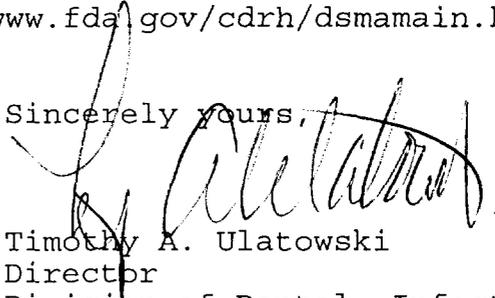
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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: 1K991376

Device Name: DAHEDI Insulin Infusion Pump

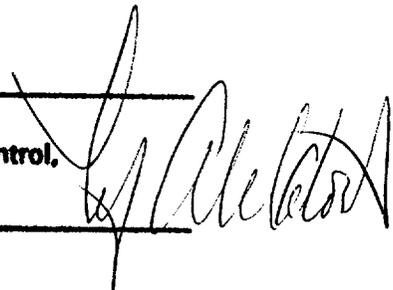
Indications For Use: The DAHEDI Insulin Infusion Pump is intended for the controlled delivery of insulin as prescribed by a physician.

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)

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



Prescription Use
(Per 21 CFR 801.19)

OR

Over-The-Counter Use _____