OCT 2 9 2002

510(k) Summary
H-TRONplus Insulin Infusion Pump

DISETRONIC

K 023471 Decision Date _____

Submitter: Disetronic Medical Systems AG
Kirchbergstrasse 190, Postfach
CH-3401 Burgdorf, Switzerland

Contact: Sandra Soniec, Phone +41 34 424 4111

Trade/Proprietary Name: Disetronic H-TRONplus Insulin Infusion Pump

Common/Usual Name: Insulin Infusion Pump and Accessories

Classification Name: Infusion Pump

Substantial Equivalence

The modified H-TRONplus Insulin Infusion Pump is substantially equivalent to H-TRONplus Insulin Infusion Pump, K973044.

Device Description

The Disetronic H-TRONplus Insulin Infusion Pump is an ambulatory, battery operated pump that administers small quantities of insulin to the patient. It is compact, shock resistant and has easy to feel buttons to maximize patient convenience. The pump housing is made of impact resistant plastic. The total system consists of the pump, piston rod, cartridge and adapter. The H-TRONplus Insulin Infusion Pump is compatible with commercially available subcutaneous administration sets with standard female luer connectors.

Insulin delivery is accomplished through the reservoir piston mechanism. The piston is advanced by means of a DC motor driving a rubber stopper forward into the cartridge. The frequency of the motor revolution is controlled by the microprocessor according to the information programmed by the user or his or her health care provider. The rate of the hourly basal infusion for twenty-four hours, subsequent boluses and any temporary increase or reduction in the basal rate can be simply entered using the three 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 directly on the pump.

Indications for Use

The Disetronic H-TRONplus 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. They must be able to adjust their insulin supply to varying needs depending on actual blood glucose levels, planned meals, physical activities, etc. 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.

Technological Characteristics

The modifications made to the H-TRONplus Insulin Infusion Pump have not affected the technological characteristics. Therefore, the modified H-TRONplus Insulin Infusion Pump has the same technological characteristics as the predicate device.

Performance Data

The Disetronic H-TRONplus Insulin Infusion Pump has been designed and tested in accordance with IEC 60601-2-24 of the International Electrotechnical Commission: 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 IEC 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.

Conclusion

Based on the design equivalency and performance and safety testing, Disetronic Medical Systems has determined that the modified H-TRONplus Insulin Infusion Pump is substantially equivalent to the H-TRONplus Insulin Infusion Pump, K973044.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2002

Disteronic Medical Systems AG
C/O Mr. David E. Chadwick
Director, Regulatory Affairs
Disetronic Medical Systems, Incorporated
5151 Program Avenue
St. Paul, Minnesota 55112-1014

Re: K023471
Trade/Device Name: H-TRONplus Insulin Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 10, 2002
Received: October 15, 2002

Dear Mr. Chadwick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) File Number: K023471

Device Name: Disetronic H-TRONplus Insulin Infusion Pump

Indications For Use:
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steven Naraian for Tat Ciccanti 10/29/02

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

510(k) Number: K023471

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)