9 510(k) Summary

K021725

9.1 Trade/Proprietary Name

Disetronic D-TRON Insulin Infusion Pump

AUG 0 2 2002

9.2 Common/Usual Name

Infusion Pump and Accessories

9.3 Classification Name

Infusion Pump

9.4 Substantial equivalence

The modified Disetronic D-TRON Insulin Infusion Pump is substantially equivalent to the currently marketed D-TRON Pump K994186.

9.5 Device Description

The Disetronic D-TRON Insulin Pump is an ambulatory, battery operated pump that administers small quantities of insulin to the patient. It is compact, shock resistant and fulfills the requirements for IP X7 to maximize patient convenience. The pump housing is made of impact resistant plastic. The total system consists of the pump, adapter and custom reservoir kit. The 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 stepper 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 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 directly on the pump.

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.

The D-TRON Insulin Infusion pump is equipped with an IR-Interface in order to enable data transmissions between the pump and a personal computer. The DiaLog PC-Software facilitates the monitoring and programming of the pump settings. Current pump settings can be displayed on the computer monitor, adjustments can be made and re-stored into the pump.

9.6 Indications for Use

The Indications for Use and Intended Use have not changed.

9.7 Technological Characteristics

The technological characteristics have not been affected by these modifications.

9.8 Performance Data

The Disetronic D-TRON 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 an therefore the specifications fully address pump performance. The device modifications are consistent with the requirements of these standards.

9.9 Conclusion

Based on the design equivalency and performance and safety testing, Disetronic Medical Systems has determined that the implementation of the DiaLog PC software for the Disetronic D-TRON Insulin Infusion Pump is substantially equivalent to the devices currently marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sandra Soniec
Manager Regulatory Affairs
Disetronic Medical Systems AG
Kirchbergstrasse 190, Postfach
CH-3401 Burgdorf,
SWITZERLAND

AUG 0 2 2002

Re: K021725
Trade/Device Name: Distetronic D-Tron Insulin Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: July 9, 2002
Received: July 11, 2002

Dear Ms. Soniec:

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.

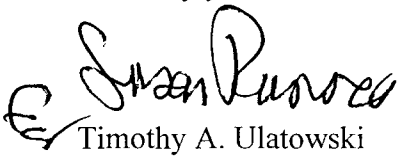
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

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:

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)

Patricia Cusenta

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K021725

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