DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2004

Disetronic Medical Systems AG
C/O Mr. Scott Thiel
Regulatory Affairs
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250

Re: K043000
Trade/Device Name: D-TRONplus Insulin Infusion Pump
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 29, 2004
Received: November 1, 2004

Dear Mr. Thiel:

This letter corrects our substantially equivalent letter of December 1, 2004 regarding the incorrect Indications for Use statement that was sent to you.

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 (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.

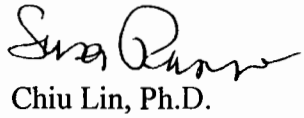
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K043000

Device Name: D-TRONplus insulin infusion pump

Indications For Use:

The Disetronic D-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 professionals experienced in insulin pump therapy.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K043000

DEC - 1 2004

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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1) Submitter name, address, contact

Submitted by:

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

United States Contact Person:

Scott Thiel
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250
317-521-3362
scott.thiel@roche.com

Date Prepared: October 29, 2004

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2) Device name

Proprietary name: D-TRONplus
Common name: Insulin infusion pump and accessories
Classification name: Pump, infusion, insulin
Product Code: LZG

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3) Predicate device

We claim substantial equivalence to the following legally marketed insulin infusion pumps:

- Disetronic D-TRONplus Insulin Infusion Pump (K#022831)

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4) Device Description

The D-TRONplus Insulin Infusion Pump is an external, portable insulin pump designed for continuous delivery of insulin. The design allows settings of 0.0 to 25.0 units in 0.1 unit increments of U100 insulin per hour in basal rates and up to 25.0 units of U100 insulin per bolus in 0.1, 0.2, 0.5, or 1.0 unit increments.

Continued on next page

K[illegible]

510(k) Summary, Continued

5) Intended use

The Disetronic D-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 professionals experienced in insulin pump therapy.

6) Data demonstrating substantial equivalence

Testing of the D-TRONplus demonstrated that the device meets the requirements for its intended use. The data also demonstrates that the D-TRONplus is substantially equivalent to the predicate device.