K033892

MAR - 9 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.

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: December 12, 2003

2) Device name

Proprietary name: Ultraflex Infusion Set
Common name: subcutaneous infusion set
Classification name: intravascular administration set
Product Code: FPA

3) Predicate device

We claim substantial equivalence to the current legally marketed version of the same device.

4) Device Description

The Ultraflex is a disconnectable infusion set with soft cannula perpendicular to the adhesive, for transfusion of insulin into the subcutaneous tissue. The unit is designed to interface with commercially available insulin infusion pumps with suitable connections. The insulin infusion pump systems are designed to control the delivery of insulin as prescribed by a health care professional. The system (infusion set, insulin infusion pump, and insulin) is indicated for patients with insulin dependent diabetes mellitus.

5) Intended use

Ultraflex™ is an infusion set for the subcutaneous infusion of insulin administered with microdosage insulin pumps.

Continued on next page

6) Data demonstrating substantial equivalence	Testing of the modified Ultraflex Infusion Set demonstrated that the device meets the requirements for its intended use. The data also demonstrates that the Ultraflex Infusion Set is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

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

Re: K033892
Trade/Device Name: Ultraflex Infusion Set
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 12, 2003
Received: December 16, 2003

Dear Mr. Thiel:

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), please contact the Office of Compliance at (301) 594-4618. 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,

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

Enclosure

K033892

Indications for Use Statement

510(k) Number (if known):
Device Name: Ultraflex Infusion Set

Indications for Use:

Ultraflex™ is an infusion set for the subcutaneous infusion of insulin administered with microdosage insulin pumps.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

William M. Burdick Sr
Irene Naveau

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

510(k) Number: K033892 lwmB
K033892