

OCT 28 2003

SECTION C. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, this 510(k) Summary is provided.

Submitter: Medtronic MiniMed, 18000 Devonshire St., Northridge, CA 91325

Contact: Mirielle Mengotto (818) 576-4112

Name of Device: Medtronic MiniMed Paradigm Countach Infusion set Model MMT-310

Predicate Devices: Maersk Medical A/S Paradigm Silhouette Infusion sets Models MMT-377, 378, 379, 380 (Premarket notification K002138)

Description of the Device: The Medtronic MiniMed Paradigm Countach infusion set Model MMT-310 is a disposable, single-use infusion set intended for use with Medtronic MiniMed external micro-infusion pumps. The Paradigm Countach is an infusion set that uses a cannula with a disconnect.

Intended Use of the Device: The Paradigm Countach infusion set is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The set is not intended nor indicated for use with blood or blood products.

Comparison of the Technological Features of the New Device and Predicate Device: The Paradigm Countach infusion set is substantially similar to the lawfully marketed predicate device. Both sets are intended for subcutaneous delivery of insulin from the infusion pump to the pump user and attaches proximally to a reservoir by means of a proprietary plastic connector, and insert distally into the device user's subcutaneous tissue with a removable stainless steel needle and a flexible catheter.



Gerda Resch
Manager, Regulatory Affairs
Medtronic MiniMed



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 28 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Mirielle Mengotto
Senor Regulatory Affairs Specialist
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325-1219

Re: K032484

Trade/Device Name: Medtronic MiniMed Paradigm Countach Infusion Set Model
MMT-310
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA, FPK
Dated: August 1, 2003
Received: August 12, 2003

Dear Ms. Mengotto:

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

K032484

INDICATIONS FOR USE

510(k) Number:

Device Name:

Medtronic MiniMed Paradigm Countach Infusion set Model MMT-310

Indications for Use:

The Paradigm Countach infusion set is intended for the subcutaneous infusion of medicine, including insulin, from an infusion pump and reservoir. The set is not intended nor indicated for use with blood or blood products.

David R. Street for PXC

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

510(k) Number: K032484

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

or

Over-the-Counter Use _____