K032005



AUG 2 2 2003

## Section C. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, a 510(k) Summary follows:

**Submitter:** Medtronic MiniMed 18000 Devonshire Street Northridge California 91325

**Contact:** Mirielle Mengotto (818) 576-4112

**Name of Device:** Medtronic MiniMed Paradigm™ Reservoir Model MMT-332

**Predicate Device:** Medtronic MiniMed Paradigm™ Reservoir Model MMT-326

**Description of the Device:** The Medtronic MiniMed Paradigm Reservoir Model MMT-332 is a disposable, single use medication container intended for use with the Medtronic MiniMed external micro infusion pumps. The reservoir shall be packaged together with a plunger rod and a transfer guard for use in filling the reservoir from a medication vial.

The modifications which are the subject of this premarket notification have no untoward effect on the safety and effectiveness of the device.

**Intended Use of the Device:** The Medtronic MiniMed Paradigm Reservoir MMT-332 is indicated for the subcutaneous infusion of medication, including insulin, from the Paradigm family of infusion pumps and infusion sets. The reservoir is not indicated for use with blood.

**Comparison of the Technological Features of the New and Predicate Devices:** The new device is substantially equivalent to the lawfully marketed predicate device. They differ in volume, filling mechanism, and infusion set connector.

8/18/03

Gerda Besch — Date
Manager Regulatory Affairs
Medtronic MiniMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

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

Re: K032005
Trade/Device Name: Medtronic MiniMed Paradigm Reservoir MMT-332
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: June 26, 2003
Received: June 30, 2003

Dear Ms. Mengotto:

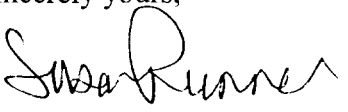
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032005

# INDICATIONS FOR USE

**510(k) Number:**

**Device Name:** Medtronic MiniMed Paradigm Reservoir MMT-332

**Indications for Use:** The Medtronic MiniMed Paradigm Reservoir MMT-332 is indicated for the subcutaneous infusion of medication, including insulin, from the Paradigm family of infusion pumps and infusion sets. The reservoir is not indicated for use with blood.

Patricia Cascante

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

510(k) Number: K032005

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use** ✓ **or** **Over-the-Counter Use** _____
(Per 21 CFR 801.109)