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SECTION C. 510(k) Summary

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

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

Contact: Jodie Rogers (818) 576-5708

Name of Device: Medtronic MiniMed® Paradigm™ Leapfrog II Infusion Set

Predicate Device: Unomedical A/S (formerly Maersk Medical), Paradigm™ Quick-set® Infusion Sets, models MMT-396, MMT-397, MMT-398, and MMT-399, and the Avail Medical Products Inc., Paradigm™ Sof-Site™ Infusion Set, models MMT-359S6, MMT-359M6, MMT-359L6, MMT-359S9, MMT-359M9, and MMT-359L9.

Description of the New Device: The Medtronic MiniMed® Paradigm™ Leapfrog II Infusion Set, models MMT-802S1, MMT-802L1, MMT-802S2, MMT-802L2, MMT-804S1, MMT-804L1, MMT-804S2, and MMT-804L2, are single use infusion administration sets intended for use with an external infusion pump, such as the Medtronic MiniMed® infusion pump.

The infusion administration set attaches proximally to a medication reservoir by means of a proprietary connector and is inserted into the subcutaneous tissue of the user distally through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP). Fluid is administered through multi-layer tubing to an indwelling catheter. The indwelling catheter is introduced into the subcutaneous tissue by means of a removable introducer needle. The introducer needle is housed in a plastic needle hub and protected by a plastic needle guard. The needle guard is removed before insertion.

The indwelling catheter is affixed to a plastic base unit. The plastic base unit functions as a site for connection and disconnection. The adhesive patch is integral to the base and is used to secure the unit to the user.

Intended Use of the New Device: The Medtronic MiniMed® Paradigm™ Leapfrog II Infusion Set, models MMT-802S1, MMT-802L1, MMT-802S2, MMT-802L2, MMT-804S1, MMT-804L1, MMT-804S2, and MMT-804L2 are 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.

®MiniMed and Quick-set are Registered Trademarks of Medtronic MiniMed
™ Paradigm and Sof-site are Trademarks of Medtronic MiniMed

Comparison of the Technological Features of the New Device and Predicate Devices
The modified device and the lawfully marketed predicate devices contain similar materials of construction. Features of the modified device are comparable to those of the predicate devices with the exception of the modified attachment mechanism that offers multiple alignments and locking sites for the attachment to the site connection. This modification does not affect the safety or effectiveness of the device.

Signed,

Mark Faillace, Sr. Director Regulatory Affairs and Product Reporting

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2005

Ms. Jodie Rogers, B.S.
Regulatory Affairs Specialist
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325-1219

Re: K052432
Trade/Device Name: Medtronic MiniMed Paradigm Leapfrog II Infusion Set, Models MMT-802S1, MMT-802L1, MMT-802S2, MMT-802L2, MMT-804S1, MMT-804L1, MMT-804S2, and MMT-804L2
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: September 2, 2005
Received: September 6, 2005

Dear Ms. Rogers:

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 (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/industry/support/index.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

INDICATIONS FOR USE

510(k) Number:

Device Name: Medtronic MiniMed Paradigm Leapfrog II Infusion Set, models MMT-802S1, MMT-802L1, MMT-802S2, MMT-802L2, MMT-804S1, MMT-804L1, MMT-804S2, and MMT-804L2

Indications for Use: The Medtronic MiniMed Paradigm Leapfrog II Infusion Set is indicated for the subcutaneous infusion of medicine, including insulin, from a Medtronic MiniMed infusion pump.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

sion Sign-Off)
ivision of Anesthesiology, General Hospital,
nfection Control, Dental Devices

510(k) Number K052432