JUN 17 2003

K030531

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: Mark Faillace (818) 576-5616

Name of Devices: Medtronic MiniMed Paradigm Model 512 Insulin Pump and BD Paradigm Link Glucose Monitor

Predicate Devices: Medtronic MiniMed Paradigm Model 511 Insulin Pump, BD Logic Glucose Monitor and Medtronic MiniMed Model 7304 ComLink

Description of the Devices:

The Paradigm Model 512 external insulin pump is an ambulatory, battery operated, rate-programmable microinfusion pump, designed for continuous delivery of insulin. A reservoir is driven by a drive motor to deliver preset basal profiles and patient programmed bolus amounts of insulin through infusion sets into subcutaneous tissue. This pump incorporates new software improvements over the predicate model and is designed to allow installation of upgraded software with new features through radio frequency telemetry without the need to replace any pump components.

The BD Paradigm Link Blood Glucose Monitor is an *in-vitro* diagnostic device for use in the quantitative measurement of glucose in capillary blood collected from fingertips. The BD Paradigm Link™ is designed to be simple and easy to use. It provides accurate blood glucose test results in 5 seconds while requiring a very small (0.3 µL) sample.

When the BD Paradigm Link Glucose Monitor is used together with the Medtronic MiniMed 512 External Insulin Pump, blood glucose test values obtained using the BD Paradigm Link Glucose Monitor can be automatically transmitted to the insulin pump for use in the pump's Bolus Wizard feature. Consumers or healthcare practitioners may also use the meter as a communication device to facilitate transfer of information between the pump and a personal computer.

The Paradigm Model 512 pump is restricted to sale by, or on the order of, a physician. The Paradigm Link Glucose Monitor is intended for over-the-counter use.

Intended Use of the Devices:

Model 512 Insulin Pump:

The Medtronic MiniMed Paradigm Model 512 Insulin Pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

BD Paradigm Link Glucose Monitor:

The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.

Model 512 Insulin Pump and BD Paradigm Link Glucose Monitor:

When used together, the BD Paradigm Link Glucose Monitor can automatically telemeter glucose values to the Model 512 Insulin Pump using radio frequency communication. The glucose value received by the Model 512 Insulin Pump is used as the default glucose value by the pump's Bolus Wizard feature if the Bolus Wizard is used within 12 minutes of the glucose value transmission.

The BD Paradigm Link Glucose Monitor can also serve as a radio frequency interface to allow communication between the Model 512 Insulin Pump and a personal computer running the appropriate Medtronic MiniMed communications software.

Comparison of the Technological Features of the New Devices and Predicate Devices:

The Model 512 and Model 511 have similar materials and basic design. The new device contains additional features compared to the predicate device. These additional features include a Bolus Wizard function and the ability to receive glucose values transmitted by the BD Paradigm Link Glucose Monitor.

510(k) Summary *(Continued)*

The BD Paradigm Link and BD Logic Glucose Monitors also have similar materials and basic design. The new device has additional circuitry and software modifications that allow it to transmit glucose values to the Model 512 Insulin Pump and to facilitate transfer of data between the Model 512 Insulin Pump and a personal computer running the appropriate Medtronic MiniMed communications software.

5/12/03

Mark Faillace
Senior Director, Device Regulatory Affairs and Quality Assurance
Medtronic MiniMed

Date

™ Paradigm 512 is a Trademark of Medtronic MiniMed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2003

Mr. Mark J. Faillace
Senior Director, Device RA/QA
Medtronic MiniMed
18000 Devonshire Street
Northridge, California 91325

Re: K030531
Trade/Device Name: Medtronic MiniMed Paradigm Model 512 Insulin Pump and the BD Paradigm Link™ Glucose Meter
Regulation Number: 880.5725, 862.1345
Regulation Name: Infusion Pump, Glucose Test System
Regulatory Class: II
Product Code: LZG, NBW
Dated: May 13, 2003
Received: May 14, 2003

Dear Mr. Mark J. Faillace:

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

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

INDICATIONS FOR USE

510(k) Number: K030531

Device Names: Medtronic MiniMed Paradigm Model 512 Insulin Pump and BD Paradigm Link Glucose Monitor

Indications for Use:

Model 512 Insulin Pump:

The Medtronic MiniMed Paradigm Model 512 Insulin Pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

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

BD Paradigm Link Glucose Monitor:

The BD Paradigm Link Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in whole blood. It is intended for use by people with diabetes mellitus in the home as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

The BD Paradigm Link Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in whole blood samples obtained from the fingertip.

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

Model 512 Insulin Pump and BD Paradigm Link Glucose Monitor:

When used together, the BD Paradigm Link Glucose Monitor can automatically telemeter glucose values to the Model 512 Insulin Pump using radio frequency communication. The glucose value received by the Model 512 Insulin Pump is used as the default glucose value by the pump's Bolus Wizard feature if the Bolus Wizard is used within 12 minutes of the glucose value transmission.

INDICATIONS FOR USE (*CONTINUED)*

The BD Link Glucose Monitor can also serve as a radio frequency interface to allow communication between the Model 512 Insulin Pump and a personal computer running the appropriate Medtronic MiniMed communications software.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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