NOV 1 8 2003

K031541

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 Street Northridge, CA 91325

Contact: Gerda Resch, Regulatory Affairs; (818) 576-4198; gerda.resch@medtronic.com

Name Of Device: Medtronic MiniMed ParadigmPAL, model 7330,

Predicate Device: Com-Link™ Communication System model 7304 and model 7311

Description Of The Device: The Medtronic MiniMed ParadigmPAL is data transfer software designated by Medtronic MiniMed to interface with hardware models 7304 (ComLink) and HS-3222 (Paradigm Link); personal computer and a Paradigm insulin infusion pump.

The ParadigmPAL system is designed for use with Medtronic MiniMed infusion pumps (model 512 and model 712).

Intended Use Of The Device: The Medtronic MiniMed ParadigmPAL (model 7330) is intended for use by patients at home and clinicians in a medical office setting in programming insulin basal delivery patterns, insulin delivery rates and current basal rates in effect on the pump. It is intended to communicate with devices that utilize Paradigm pump compatible RF telemetry (i.e. MMT-512).

Comparison Of The Technological Features Of The New Device And Predicate Device: The technological features of the new device do not differ significantly from the predicate device. The minor difference is that the software will permit both the upload and download of information to the pump through a Medtronic MiniMed ComLink or Paradigm Link glucose meter. The Com-Link Communication System software only permits download of information from the pump and does not allow the user to upload setting to the pump.

Gerda Resch, RAC
Manager, Regulatory Affairs
Medtronic MiniMed

5.15.03
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2003

Medtronic MiniMed, Incorporated
Ms. Gerda Resch
Manager, Regulatory Affairs
18000 Devonshire Street
Northridge, California 91325-1219

Re: K031541
Trade/Device Name: ParadigmPAL, Model MMT-7330
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 20, 2003
Received: October 22, 2003

Dear Ms. Resch:

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.

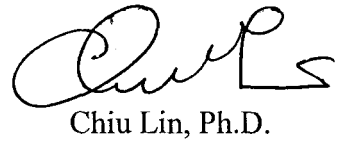
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

INDICATIONS FOR USE

510(k) Number:

Device Name: Medtronic MiniMed ParadigmPAL model 7330

Indications For Use: The Medtronic MiniMed ParadigmPAL (model 7330) is intended for use by patients at home and clinicians in a medical office setting as a tool to save and adjust Medtronic MiniMed Paradigm pump settings using a personal computer.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number: K031541