DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

JAN 1 0 2017

Re: K031390
Trade/Device Name: Medtronic MiniMed Paradigm Model 712 Insulin Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: April 30, 2003
Received: May 2, 2003

Dear Ms. Mirielle Mengotto:

This letter corrects our substantially equivalent letter of Jul 23, 2003.
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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809]), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K031390

Device Name: Medtronic MiniMed Paradigm Model 712 Insulin Pump

Indications for Use: The Medtronic MiniMed Paradigm Model 712 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.

Adriana Cucuzzella
(Division Sign-Off)
Division of Anesthesiology, Gen
Infection Control, Dental Device

510(k) Number: K031390

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

JUL 2 3 2003

SECTION D. 510(k) Summary for K031390

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 Model 712 Insulin Pump

Predicate Device: Medtronic MiniMed Paradigm Model 511 Insulin Pump

Description of the Device: The Paradigm Model 712 is an external, portable insulin pump, designed for continuous deliveryof insulin. It is designed to deliver 0.00 to 35.00 units of U100 insulin per hour in basal rates and up to 25.00 units of U100 insulin per meal bolus. This pump will include a bolus estimator feature that can be tailored to an individual user's insulin sensitivity, insulin to carbohydrate ratio, and target BG (Blood Glucose). Also, there is a BG reminder feature, allowing the user to set daily and post-bolus reminders to check BG readings. The insulin programming step size will allow users to program insulin delivery in steps of 0.1 units for boluses and 0.05 units for basal delivery.

The Model 712 accommodates a proprietary 3.0 ml reservoir. This new reservoir mates with the existing and future Paradigm infusion sets.

Intended Use of the Device: The Medtronic MiniMed Paradigm Model 712 Insulin Pump is intended for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Comparison of the Technological Features of the New Device and Predicate Device: The new and predicate devices have similar materials and basic design. The new device will have a larger case than Paradigm Model 511 and contains software modifications including the Bolus Wizard, as compared to the predicate, which does not.

Gerda Resch
Manager, Regulatory Affairs
Medtronic MiniMed

4/30/03
Date

™ Paradigm Model 712is a Trademark of Medtronic MiniMed