MiniMed®

JUN 8 1999

K990801

## Section D. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, this 510(k) Summary is provided:

**Submitter:** MiniMed® Inc. 12744 San Fernando Rd., Sylmar, California 91342.

**Contact:** Don Selvey, Department of Clinical Research and Regulatory Affairs (818) 362-5958, 3011; (520) 527-0107 (v/f).

**Name of Device:** MiniMed Model 508 Insulin Pump

**Predicate Device:** MiniMed Model 507C Insulin Pump

**Description of the Device:** The 508 external insulin pump is a rate-programmable syringe infusion pump, designed for continuous delivery of insulin, at set and variable rates, as prescribed by the user's physician. The 508 is restricted to sale by, or on the order of, a physician. It is not intended or indicated for the delivery of blood or blood products. The principal modifications described in this submission are intended to allow the pump user more options for programming, and to enhance the convenience of the device.

Convenience features include a vibrating and escalating audible alarm; a low insulin alert; new keypad; and a new LCD screen. New programming features include the addition of two personal delivery patterns to enhance delivery options; the ability to program a bolus on square wave to enable the user to program a bolus while an extended (or square wave) bolus is being administered; child block to help prevent reprogramming by younger users; and limited remote programming by radio frequency (RF), which allows users to deliver an audio bolus, suspend or restart the pump.

The new device also has a flash memory instead of a read only memory, which holds data in the event the pump batteries are removed for more than two hours.

**Intended Use of the Device:** The 508 is intended for continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. It is not intended for use with blood or blood products.

**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 devices have similar materials, product design, and energy source.

Don Selvey 3-5-99

Don Selvey date
Senior Regulatory Affairs Specialist
Department of Clinical and Regulatory Affairs
MiniMed Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 8 1999

Mr. Don Selvey
Senior Regulatory Affairs Specialist
Department of Clinical and Regulatory Affairs
MiniMed® Incorporated
12744 San Fernando Road
Sylmar, California 91342

Re: K990801
Trade Name: MiniMed® 508 Insulin Pump
Regulatory Class: II
Product Code: LZG
Dated: March 9, 1999
Received: March 10, 1999

Dear Mr. Selvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

**510(k) Number:**

**Device Name:** MiniMed Model 508 Insulin Pump

**Indications for Use:** The MiniMed insulin pump, model 508, is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Patricia Cucinotta
**(Division Sign-Off)**
**Division of Dental, Infection Control, and General Hospital Devices**
510(k) Number K990501