JUN 23 1999

K991013

MiniMed®

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 Road, Sylmar, California 91342

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

Name of Device: MiniMed Model 407C Infusion Pump

Predicate Device: MiniMed Model 507C Insulin Pump; MiniMed 404-SP Infusion Pump

Description of the Device: The 407C external pump is a syringe-reservoir, rate-programmable pump designed for infusion of medication appropriately labeled for subcutaneous administration, at set and variable rates, as prescribed by the user's physician. The 407C is restricted to sale by or on the order of a physician. It is not intended nor indicated for the delivery of blood or blood products. The principal modifications described in this submission are:

1) The device is indicated for use with medication labeled for subcutaneous administration. 2) A Low Reservoir Alert feature has been incorporated that will sound when the reservoir plunger reaches the point where approximately 0.200 ml of medication remains. 3) A 'Take a Break' Bolus feature has been added to deliver a bolus before disconnecting from the pump to help the patient remain above the minimum therapeutic level of the medication for the duration of the break. 4) Three lockout levels have been incorporated so that some features will not be accessible to the patient. 5) The Bolus feature and the 'Take a Break' Bolus feature can be turned on and off. 6) A Suspend/Storage Mode has been incorporated in which no recurring alert will remind the user of that condition. 7) The medication concentration feature has been eliminated. The medication administration rate will be adapted by delivery rate of the pump only. 8) The square wave bolus and dual wave bolus have been eliminated. A normal bolus can be administered. 9) The temporary basal rate feature has been eliminated. 10) Forty-eight basal rates have been replaced by a single rate. 11) The Auto Off and Audio Bolus features have been eliminated. 12) The LCD has been revised so that the word RATE will replace BASAL, PROG will replace SET, and ML will replace U for the amount of medication displayed. 13) Two new icons, a low reservoir icon and a lock icon, have been incorporated.

The modifications which are the subject of this premarket notification have no untoward effect on the safety and effectiveness of the device.

Intended Use of the Device: The MiniMed 407C Infusion Pump is intended for infusion of medication labeled for subcutaneous administration, at set and variable rates, for therapies including chemotherapy, antibiotic therapy, and controlled analgesia. 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 407C do not differ significantly from the 404-SP and the 507C infusion pumps. The devices have similar materials, product design, and energy source. The 407C and the 404-SP are intended for infusion of medication labeled for subcutaneous administration, while the 507C is intended only for subcutaneous insulin delivery.

3-24-99

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

• 800-933-3322 • (818) 362-5958 • FAX (818) 362-1460 • Web Site: http://www.minimed.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 1999

Mr. Don Selvey
Senior Regulatory Affairs Specialist
Department of Clinical and Regulatory Affairs
MiniMed, Incorporated
12744 San Fernando Road
Sylmar, California 91342-3728

Re: K991013
Trade Name: MiniMed® Model 407C Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 25, 1999
Received: March 26, 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 407C Infusion Pump

Indications For Use: The MiniMed 407C Infusion Pump is indicated for infusion of medication labeled for subcutaneous administration, at set and variable rates, for therapies including chemotherapy, antibiotic therapy, and controlled analgesia.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991013