MiniMed

K972107

Part F. 510(k) Summary

In accordance with the requirements of SMDA 1990, and 21 CFR 807.92, a 510(k) Summary follows:

AUG 15 1997

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

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

Name of Device: MiniMed model 507c Insulin Pump.

Predicate Device: MiniMed model 507 Insulin Pump.

Description of the Device: The 507c 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 507c 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:

1) Several of the pump electronics have been integrated into an application specific integrated circuit (ASIC) Approximately 12 K of memory has been added to the Random Access Memory. The device now stores the last 90 days of basal and bolus delivery information, compared with three days in the 507 pump. The memory will also store the last 200 events and last 50 alarms, as well as the device serial number; 2) The basal rate option has been increased. The user may now program up to 48 basal rates, compared with 12, 3) The delivery capacity has been increased. The 507c may deliver up to 35.0 units per hour, compared to 25.0; 4) A screen has been added to account for the priming bolus. This is a new feature that is intended to discount from the delivery history insulin used to prime the infusion set(s) but not actually delivered to the patient; 5) A "Dual Wave" bolus delivery pattern has been added, which allows the device user to program the pump to deliver a percentage of the bolus immediately, with the rest to be delivered in a diminishing pattern over time; 6) A new screen has been added to allow the user to choose the language s/he wishes the pump to use in presenting messages. Currently, only English is offered; however, in the future other language options will be provided. The likely languages include French, German, Spanish, Italian, and possibly others. This is designed to address the needs of device users more comfortable with languages other than English.

Intended Use of the New Device: The 507c 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 from the predicate device. Both devices have the same materials, product design, and energy source. The electronics have been enhanced in the new device.

Don Selvey 7-31-97

Don Selvey date
Regulatory Affairs
MiniMed Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 1997

Mr. Don Selvey
Regulatory Affairs
MiniMed Technologies, Incorporated
12744 San Fernando Road
Sylmar, California 91342

Re: K972107
MiniMed Infusion Pump, Model 507C
Regulatory Class: II
Product Code: LZG
Dated: June 3, 1997
Received: June 5, 1997

Dear Mr. Selvey:

This letter corrects our substantially equivalent letter dated August 1, 1997.

We have reviewed your Section 510(k) notification of intent to market the device reference above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (act). The general controls provisions of the act include requirements for registration, listing of devices, good manufacturing practices, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulation.

Under Section 522(a) of the act, manufacturers of certain types of devices identified by the Act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under Section 522(a)(1)(A) the device cleared for marketing by this letter as requiring postmarket surveillance.

Within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you are required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is attached.

Submit five (5) copies to:

Center for Devices and Radiological Health
Postmarket Surveillance Studies Document Center
Suite 405 (HFZ-544)
1801 Rockville Pike
Rockville, Maryland 20852

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. You should not begin your postmarket surveillance study of this device until the protocol has been approved. Data generated under an unapproved protocol may not satisfy your obligation under section 522. Please note that you must continue to collect and report data needed to maintain compliance with Medical Device Reporting regulations (21 CFR 803).

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete and FDA approved postmarket surveillance study consistent with the protocol will be considered violations of section 522. In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the Act (21 U.S.C. 331 (q)(1)(C). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under

section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

If you have questions specifically concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch at (301) 594-0639.

In addition, on August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirement of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-326) at (301) 594-4639. Other general information on your responsibilities under the act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

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

INDICATIONS FOR USE

510(k) Number: K972107

Device Name: MiniMed insulin pump, model 507c

Indications for Use: The MiniMed insulin pump, model 507c, 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)

(Division Sign-Off) Patricia Cucanda
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972107

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