JAN 18 2000

K991936

MiniMed

Section D. 510(k) Summary

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

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

Contact: Jennifer Lyons, Regulatory Affairs (818) 362-5958, ext. 3111

Name of Device: MiniMed 3.0 ml Reservoir Model 103/193

Original Device: Single Use Syringe Model 103

Description of the Device: The MiniMed 3.0 ml Reservoir Model 103/193 is a single use 3.0 ml piston syringe consisting of a hollow barrel, movable plunger with O-rings for sealing, and a male Luer lock fitting at the distal end of the barrel. The device is used in conjunction with an external infusion pump and infusion set to deliver medication subcutaneously. The male Luer lock fitting of the reservoir is connected to the female Luer fitting of an infusion set, and the reservoir is placed in an external infusion pump. The 103/193 reservoir is designed for use with MiniMed infusion pumps. Models 103 and 193 differ only in end configuration and packaging. The 103 is individually packaged with a covered needle attached to the male connector, while the 193 is multi-packed with a vented cap instead of a needle.

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 3.0 ml Reservoir Model 103/193 is intended for use for the infusion of medicine, including insulin, from an external infusion pump. The reservoir is not intended for use with blood or blood products.

Comparison of the Technological Features of the Modified and Original Devices: The modified device is substantially equivalent to the lawfully marketed original device. The differences between the modified and original devices are: 1) The name of the device has been changed from the Single Use Syringe Model 103 to the MiniMed 3.0 ml Reservoir Model 103/193. 2) The O-ring material has changed from a rubber compound to silicone rubber. 3) The lubricant has changed from a silicone fluid to a silicone-fluorosilicone fluid. 4) Model 193 uses bulk packaging as opposed to single packaging. 5) Model 193 has a vented cap on the distal end instead of a needle. 6) The 1 in. needle of the original device was changed to a 0.5 in. needle in Model 103. 7) The assembly process has been automated.

Jennifer Lyons 6/8/99

Jennifer Lyons — Date
Regulatory Affairs Specialist
Regulatory Affairs
MiniMed Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed™, Incorporated
12744 San Fernando Road
Sylmar, California 91342-3728

Re: K991936
Trade Name: MiniMed 3.0 ml Reservoir
Regulatory Class: II
Product Code: FRN
Dated: October 18, 1999
Received: October 20, 1999

Dear Ms. Lyons:

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

MiniMed™

INDICATIONS FOR USE

510(k) Number:

Device Name: MiniMed 3.0 ml Reservoir Model 103/193

Indications for Use: The MiniMed 3.0 ml Reservoir Model 103/193 is indicated for use for the infusion of medicine, including insulin, from an external infusion pump. The reservoir is not indicated for use with blood or blood products.

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 K991936