K991979

SEP 3 1999

Part C. 510(k) Summary

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

Contact: Don Selvey, Regulatory Affairs (818) 362-5958, 3011; (480) 704-8070 (v/f)

Name of Device: MiniMed Sof-set Micro QR® infusion sets, models 320 and 321

Predicate Device: MiniMed Sof-set Ultimate™ QR infusion sets, models 315 and 316

Description of the New Device: The MiniMed Sof-set Micro QR infusion sets, models 320 and 321, are infusion administration sets, connected to a medication reservoir proximally and inserted in the subcutaneous tissue of a user distally by means of an introducer needle. The reservoir to which the infusion set attaches proximally is inserted into an external infusion pump, such as a MiniMed infusion pump.

The administration set attaches to the reservoir by means of a female Luer connector, and subcutaneously in the user through an indwelling catheter made of Fluorinated Ethylene Propylene (FEP). The tubing is made of polyvinyl chloride (PVC) with a polyolefin liner. This configuration of PVC and polyolefin has been trademarked by MiniMed as Polyfin®.

The 24 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 26 gauge introducer needle made of 304 stainless steel. The indwelling catheter and tubing share a common hub through which the introducer needle fits. The hub incorporates a winged configuration with an adhesive patch to facilitate handling of the administration set during insertion and stability following insertion. An adhesive dressing covers the wings and hub of the administration set, securing the subcutaneous catheter and infusion line to the user.

Intended Use of the New Device: The MiniMed Sof-set Micro QR is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The set is not intended nor indicated for use with blood or blood products.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device is substantially similar to the lawfully marketed predicate device. Both are intended for subcutaneous delivery of insulin or other appropriately labeled medication from an infusion pump to the pump user. Both sets attach proximally to a reservoir by means of a Luer connector, and insert distally into the device user's subcutaneous tissue with a removable stainless steel needle and flexible catheter. The materials and manufacturing processes are the same for the modified and predicate devices.

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Several differences exist between the new and predicate device:

1) The new device has a 6 mm long catheter instead of the current 9 mm version.
2) The introducer needle has been shortened by 3 mm.
3) The adhesive patch beneath the stabilizing wings has been increased in size to cover the entire underside of the wings.
4) The underside of the wing has been modified with a smoother radius to facilitate attachment of the larger adhesive patch.

These modifications do not affect the safety or effectiveness of the device.

Signed,

Don Selvey 6-9-99

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

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

Re: K991979
Trade Name: Sof-Set Mirco QR Infusion Sets, Models 320 and 321
Regulatory Class: II
Product Code: FPA
Dated: June 9, 1999
Received: June 14, 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

MiniMed®

INDICATIONS FOR USE

510(k) Number: K991979

Device Name: MiniMed Sof-set Micro QR infusion sets, models 320 and 321.

Indications for Use: The MiniMed Sof-set Micro QR infusion set is indicated for the subcutaneous infusion of medicine, including insulin, from an external infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991979

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

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