AUG 1 8 2000

K001832

MiniMed®

Section C. 510(k) Summary

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

Contact: Jennifer Lyons (818) 362-5958, Ext. 7381

Name of Device: MiniMed® Paradigm™ Sof-set Ultimate QR® infusion sets, models 317 and 318

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

Description of the New Device: The MiniMed Paradigm Sof-set Ultimate QR infusion sets, models 317 and 318, are infusion administration sets, which connect to a Paradigm medication reservoir proximally. The distal portion is inserted in the subcutaneous tissue of a user by means of an introducer needle. The reservoir to which the infusion set attaches proximally is inserted into a Paradigm infusion pump.

The infusion set attaches to the reservoir by means of a "tubing 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 Paradigm Sof-set Ultimate QR, models 317 and 318, are intended for the subcutaneous infusion of medicine, including insulin, from a MiniMed Paradigm infusion pump. The set is not intended nor indicated for use with blood.

Comparison of the Technological Features of the New Device and Predicate Device: The modified device and the lawfully marketed predicate device differ only in the type of connector that attaches the infusion set to a reservoir. The materials in the fluid path are the same for the new and predicate devices. The modification does not affect the safety or effectiveness of the device.

Signed,

Jennifer Lyons 6/15/00

Jennifer Lyons date
Regulatory Affairs Specialist
MiniMed Inc.

®MiniMed, Polyfin, Sof-set, and QR are registered trademarks of MiniMed Inc.
™Paradigm and Ultimate are Trademarks of MiniMed Inc.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2000

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

Re: K001832
Trade Name: MiniMed Paradigm Sof-set Ultimate QR Infusion sets, models 317 and 318
Regulatory Class: II and II
Product Code: FPA and FPK
Dated: June 15, 2000
Received: June 16, 2000

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 legally marketed predicate 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/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

K001832

MiniMed®

INDICATIONS FOR USE

510(k) Number:

Device Name: MiniMed Paradigm Sof-set Ultimate QR infusion sets, models 317 and 318

Indications for Use: The MiniMed Paradigm Sof-set Ultimate QR infusion sets are indicated for the subcutaneous infusion of medicine, including insulin, from a MiniMed Paradigm 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 K001832

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