K002138

AUG 2 9 2000

Section C. 510(k) Summary

Submitter: Maersk Medical A/S Infusion Devices, Aaholmvej 1-3, Osted, DK-4000 Roskilde, Denmark

Maersk Contact: Mr. John M. Lindskog, General Manager, Maersk Medical A/S Infusion Devices
Telephone: + 45 48 16 70 00

U.S. Contact: Jennifer Lyons (818) 362-5958, Ext. 7381; JenniferLy@MiniMed.com

Name of Device: Paradigm™ Silhouette® infusion set, models 377, 378, 379, 380

Predicate Device: Maersk Medical Comfort Infusion Set

Description of the New Device: The Paradigm Silhouette infusion sets are infusion administration sets, connecting to a MiniMed medication reservoir developed for use with a MiniMed Paradigm infusion pump and inserted in the subcutaneous tissue of a user.

The administration set attaches to the reservoir by means of a "tubing connector", and subcutaneously in the user through an indwelling catheter made of polytetrafluoroethylene (PTFE). The tubing is made of two layers: the inner layer is polyethylene; the outer is polyurethane. The 25 gauge indwelling catheter is introduced into the subcutaneous tissue by a removable 27 gauge introducer needle made of 304 stainless steel.

Intended Use of the New Device: The Paradigm Silhouette infusion sets are intended for the subcutaneous infusion of medication, including insulin, from a MiniMed Paradigm infusion pump. The infusion sets are neither 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 modification does not affect the safety or effectiveness of the device.

Signed,

John M. Lindskog 7/6/2000
John M. Lindskog date
General Manager
Maersk Medical A/S

®MiniMed and Silhouette are Registered Trademarks of MiniMed Inc.
™ Paradigm is a Trademark of MiniMed Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Maersk Medical A/S
C/O Ms. Jennifer Lyons
Regulatory Affairs Specialist
MiniMed, Incorporated
18000 Devonshire Street
Northridge, California 91325

Re: K002138
Trade Name: Paradigm Silhouette Infusion Set
Regulatory Class: II and II
Product Code: FPA and FPK
Dated: July 6, 2000
Received: July 17, 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 of Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number:

Device Name: Paradigm Silhouette infusion set

Indications for Use: The Paradigm Silhouette infusion sets are indicated for the subcutaneous infusion of medication, 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 K002138