

K991759

JUN 25 1999

Maersk Medical A/S
Premarket Notification - 510(k)
Contour Infusion Set



May 20, 1999

Part 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: Don Selvey (520) 527-0107 (v/f); DonS@MiniMed.com.

Name of Device: Maersk Medical Contour™ Infusion Set.

Predicate Device: Maersk Medical Comfort™ Infusion Set

Description of the New Device: The Contour Infusion Set is an infusion administration set, connecting to a medicine reservoir syringe (such as the MiniMed® reservoir, model 103, that is placed in an external infusion pump such as the MiniMed insulin pump) and inserted in the subcutaneous tissue of a user. The Maersk Medical Contour Infusion Set may be used with any microbore infusion pump reservoir which utilizes a standard Luer connector.

The administration set attaches to the reservoir/syringe by means of a female Luer 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 (cannula) made of AISI 304 stainless steel. The needle, indwelling catheter, and tubing share a common hub.

Intended Use of the New Device: The Contour infusion set is intended for the subcutaneous infusion of medicine, including insulin, from an external infusion pump. The infusion set is neither intended nor indicated for use with blood or blood products.

Comparison of the Technological Features of the New Device and Predicate Device: The Contour infusion set is substantially similar to the Comfort infusion set (a lawfully marketed predicate device). Both are intended for subcutaneous delivery of insulin or other appropriately labeled medicines 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 tissues with a removable stainless steel needle and flexible cannula. The devices are made of similar materials.

Signed,


John M. Lindskog
General Manager
Maersk Medical A/S

5-20-99
date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 25 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Maersk Medical A/S
c/o Don Selvey
Consultant
Department of Clinical and Regulatory Affairs
MiniMed Incorporated
12744 San Fernando Road
Sylmar, California 91342

Re: K991759
Trade Name: Maersk Medical Contour™ Infusion Set
Regulatory Class: II
Product Code: FPA
Dated: May 20, 1999
Received: May 24, 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 (Pre-market 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.

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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



May 20, 1999

INDICATIONS FOR USE

510(k) Number:

Device Name: Maersk Medical Contour Infusion Set

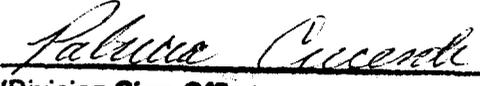
Indications for Use: The Maersk Medical Contour infusion set is indicated for subcutaneous delivery of appropriately labeled fluids or solutions from an external infusion pump.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

or

Over-the-Counter Use


(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991759