K984561
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510(K) Summary

Submitter: MRS 124 Heritage Avenue, Portsmouth, New Hampshire 03801

Contact: Joyce McDougall, General Manager, phone: (603) 427-5511 or Fax: (603) 431-1612

Trade Name: MSR Model A & Model B Subcutaneous Infusion Set
Common Name: Subcutaneous Infusion Set
Classification Name: Intravascular Administration Set

Predicate Device: Disetronic Tender Set K9972135

Device Description: The MSR Model A and Model B Subcutaneous Infusion Sets connect at the female luer connection to a reservoir containing insulin or other medications delivered by an infusion pump. The 28 gauge AISI 304 stainless steel introducer needle and 25 gauge soft cannula connected to the hub is inserted into the subcutaneous tissue . The introducer needle is removed and the hub and soft cannula remains in place. The Model B Subcutaneous Infusion Set has a 28 gauge AISI needle connected to a hub is inserted directly into the subcutaneous tissue. The cannula hub are affixed by an acrylic medical grade adhesive. The tubing is polyethylene lined polyurethane has a female Luer on one end and a connector that attaches to the hub on the other end. The tubing set portion can be removed and capped off when the pump is not in use while the hub and cannula remain in place.

Intended Use of the New Device: The MSR Model A and B Subcutaneous Infusion Sets are intended to be used to administer insulin and medications under the skin.

Comparison of the Technical Features of the New Device and Predicate Device: The intended use of the MSR Model A and Model B Subcutaneous Infusion Set is the same as the legally marketed predicate device. The instructions for use is the same as the predicate device. The MSR Model A and Model B Subcutaneous Infusion Set and the predicate device use identical materials contacting the fluid path with the exception of the connector, and hub which is identical to the another predicate device.

No significant technological differences exist between the MSR Model A and Model B Infusion Sets and the predicate device.

The adhesive used to manufacture the device is medical grade acrylic adhesive. This adhesive does not come in contact with the fluid path of the device.

The slight differences are the 90 degree insertion angle (commonly used) of various length needles at 6 mm, 8 mm, 10 mm, and 12 mm and the AISI 304 stainless steel needle availability in the MSR Subcutaneous Infusion Sets Vs the 30 degree insertion angle of the predicate device available in a soft cannula of 17 mm length.

The inner diameter of the tubing is slightly smaller at 0.36 mm in the MSR Subcutaneous Infusion Set Vs the predicate device at 0.4 mm.

The outer diameter is identical in these sets. MSR Model A and Model B Subcutaneous Infusion Set offers an additional tubing set length at 30 mm.

These differences do not affect the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 4 1999

MSR, Incorporated
C/O Ms. McNamara-Cullinane
Consultant
Medical Device Consultants, Incorporated
49 plain street
North Attleboro, Massachusetts 02760-4153

Re: K984561
Trade Name: Subcutaneous Infusion Sets, MSR Model A & B
Regulatory Class: II
Product Code: FPA
Dated: December 22, 1998
Received: December 23, 1998

Dear Ms. McNamara-Cullinane:

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

510(k) Number (if known): _____

Device Name: Model A & B Subcutaneous Infusion Sets

Indications For Use:

Model A & B Subcutaneous Infusion Set is intended to be used to administer insulin and medications under the skin.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Rebecca Cucenty
(Division Sign-Off) Frank Bitte
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K984561