K971168

510(k) SUMMARY
Syringe•Mate System

JUL 15 1997

Submitted by:
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I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
March 29, 1997

Proposed Device:
Syringe•Mate System

Predicate Devices:
Uni•Dose Infusion Pump
Baxter Multiday Infusor

Proposed Device Description:

The new device consists of a line of Syringe•Mate System infusion pumps which will be manufactured with three different fixed, flow rates:

*One Day Syringe•Mate System (4.2 mL/hr)
*Five Day Syringe•Mate System (0.8 mL/hr)
*Seven Day Syringe•Mate System (0.6 mL/hr)

Summary of Technological Characteristics of New Device to Predicate Devices

The Syringe•Mate System differs in material composition but is the same in overall design and intended use as the predicate devices.

MAR 28 1997

Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests

The biological and chemical reactivity of the new materials have been assessed using biological methods specified in ISO 10993-1 and USP Physicochemical tests. The materials were found to be acceptable for their intended use.

Data regarding the functional performance of the Syringe•Mate System have also been generated. Testing was conducted to evaluate flow rate, residual volume and pressure relief valve performance. Performance testing results indicate that the Syringe•Mate System meets or exceeds the functional requirements and supports its suitability for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Patricia S. Barsanti, RAC
Regulatory Affairs Manager
Baxter Healthcare Corporation
P.O. Box 490
Route 120 and Wilson Road
Round Lake, Illinois 60073

JUL 15 1997

Re: K971168
Trade Name: One-Day/Five-Day/Seven-Day Syringe Mate
Regulatory Class: Unclassified
Product Code: MEB
Dated: June 19, 1997
Received: June 24, 1997

Dear Ms. Barsanti:

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 current Good Manufacturing Practice requirement, 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) 594-4618. 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

510(k) Number: ~~Not Available~~ K971168

Device Name: Syringe•Mate System (Models 2C1141, 2C1142, 2C1143)

Indications for Use: The Syringe•Mate System is indicated for patients requiring slow, continuous intravenous, epidural, or subcutaneous administration of medications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) Fabricia Cucinotta
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971168

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