MERIT MEDICAL

K973230

NOV 25 1997

510(k) SUMMARY

SAFETY AND EFFECTIVENESS SUMMARY

August 25, 1997

This information of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by Name/Address:

Dennis Reigle
Regulatory Affairs Manager
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095
(801) 253-1600
(801) 253-1684 fax

Contact Person:

Same as above

Date Summary Prepared:

Device Name: Universal Dispensing Syringe

Common Name: Piston Syringe

Trade Name: Intellisystem Inflation Device and Fluid Dispensing Syringe
Monarch Inflation Device and Fluid Dispensing Syringe

Classification (if known): 80 FMF

Predicate Devices: Merit Medical Medallion Syringe

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MERIT MEDICAL

Merit Medical Systems, Inc.
510(k) Notification: Universal Fluid Dispensing Syringe
August 1997

Applicant Device Description: This is a general purpose syringe and inflation device with pressure monitoring capability.

Applicant Device Intended Use: To be used by healthcare professionals to dispense fluids to the body and monitor the pressure of that fluid.

Technological Characteristics:

Device Options			
Device:	**Description:**	**Sterile:**	**Disposable:**
Monarch	20 ml volume syringe with an electronic (transducer) pressure measurement monitor, battery powered, attached to the barrel of the syringe which has an operating range of -1 to 25 ATM. It can also dispense 0.25ml of fluid for each 180° clockwise turn of the syringe plunger handle.	Yes	Yes
Intellisystem	20 ml volume syringe with an electronic (transducer) connected to an external monitor (120 VAC) by means of a wire. It has an operating range of -1 to 25 ATM. It can also dispense 0.25ml of fluid for each 180° clockwise turn of the syringe plunger handle.	Syringe: Yes Monitor: No	Syringe: Yes Monitor: No

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 1997

Mr. Dennis Reigle
Regulatory Affairs Manager
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K973230
Universal Fluid Dispensing Syringe
Regulatory Class: II (two)
Product Code: DXT
Dated: August 25, 1997
Received: August 27, 1997

Dear Mr. Reigle:

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 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) 594-4648. 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Merit Medical Systems, Inc.
510(k) Notification:

Indications For Use:

The Universal Fluid Dispensing Syringe is Merit Medical's Monarch Syringe and Intellisystem Syringe intended to be used by healthcare professionals to inject fluids into the body and monitor the pressure of that fluid.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973230

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)