K011811

Attachment 3

510(k) Summary

AUG 2 2 2001

SAFETY AND EFFECTIVENESS SUMMARY

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

Submitted by Name / Address:	Dennis (Dan) Reigle Manager Regulatory Affairs Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4349 (direct) (801) 253-1684 (fax)
Contact Person:	Same as above
Date Summary Prepared:	July 24, 2001
Device Name:	30 ATM Monarch Syringe
Common Name:	Balloon Inflation Syringe
Trade Name:	Monarch™ Inflation Syringe Universal Fluid Dispensing Syringe
Classification (if known):	Cardiovascular
Predicate Device(s):	Monarch™ Inflation Syringe (K943597) Universal Fluid Dispensing Syringe (K973230)

Attachment 3

510(k) Summary

SAFETY AND EFFECTIVENESS SUMMARY

Device Description:

The 30 ATM Monarch™ is a 20 ml single use balloon inflation and fluid dispensing device with an integral pressure transducer, 4-bit microcomputer, back-lit LCD, threaded plunger assembly with lock/release bar, a flexible high pressure extension tube and a three-way medium pressure stopcock. The 30 ATM Monarch™ is capable of generating and monitoring pressures over a range of –1 to +30 atmospheres (-7 to + 441 PSI). The Monarch syringe dispenses .45 ml of fluid ± .07ml for each 360° turn of the syringe plunger handle.

Intended Use:

The 30 ATM Monarch™ syringe is used to inflate and deflate balloon angioplasty catheters and to measure the pressure within the balloon during the procedure. It is also used to inject fluids into the body and to monitor the pressure of that fluid.

Comparison of 30 ATM Monarch™ to Predicate Devices

	Modified Device	**Predicate Devices**	
	30 ATM Monarch (K011811)	25 ATM Monarch (K943597)	Universal Fluid Dispensing Syringe (K973230)
Materials			
• Barrel	Same as Predicate Devices	Polycarbonate	Polycarbonate
• Syringe Plunger	Same as Predicate Devices	ABS Plastic	ABS Plastic
• Syringe Plunger Tip	Same as Predicate Devices	Natural Rubber	Natural Rubber
• Tubing with Rotating Adaptor	Same as Predicate Devices	Polyurethane tubing Polycarbonate adaptor	Polyurethane tubing Polycarbonate adaptor
• Pressure Transducer Interface	Same as Predicate Devices	Black Silicone Gel	Black Silicone Gel
• Microprocessor	Same as Predicate Devices	NEC Electronics, Inc. μPD75328, 4bit CPU	NEC Electronics, Inc. μPD75328, 4bit CPU

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

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

Re: K011811
Trade Name: Monarch™ Syringe Universal Fluid Dispensing Syringe
Regulation Number: 870.1650
Regulatory Class: II (two)
Product Code: 74 DXT and 74 MAV
Dated: July 27, 2001
Received: July 30, 2001

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 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) 594-4586. 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,

James E. Dillard III
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011811

Device Name: 30 ATM Monarch Syringe

Indications For Use:

The 30 ATM Monarch syringe is used to inflate and deflate balloon angioplasty catheters and to measure the pressure within the balloon during the procedure. It is also used to inject fluids into the body and to monitor the pressure of that fluid.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011811

(Optional Format 3-10-98)