K083523

FEB - 4 2009

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Registration Number: Contact Person: Date of Preparation:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4748 (801) 253-6960 1721504 Susan Scott November 25, 2008
Subject Device	Trade Name: Common Name: Classification Name: Classification:	*Monarch™ COMPAK* Inflation Syringe & Universal Fluid Dispensing Syringe Balloon Inflation & Fluid Dispensing Syringe 74 MAV – Balloon Inflation Syringe 74 DXT – Angiographic Injector & Syringe Class II, 21 CFR § 870.1650
Predicate Devices	Trade Name: Classification Name: Premarket Notification: Manufacturer:	*Monarch™* Inflation Syringe & Universal Fluid Dispensing Syringe 74 MAV – Balloon Inflation Syringe 74 DXT – Angiographic Injector & Syringe K011811, clearance date Aug. 22, 2001 Merit Medical Systems, Inc
	Trade Name: Classification Name: Premarket Notification: Manufacturer:	*Viceroy™* Inflation Syringe with Gauge 74 MAV – Angiographic Injector & Syringe K040138, clearance date Feb. 13, 2004 Merit Medical Systems, Inc
Device Description	The subject *Monarch™ COMPAK* Inflation Syringe is a single use, balloon inflation and fluid dispensing device with an integrated pressure transducer, microprocessor, LED display, threaded plunger assembly with lock/release handle, a flexible high pressure extension tubing and a three-way stopcock. The *Monarch™ COMPAK* has a shorter barrel than the standard *Monarch™* device. It is designed to generate and monitor pressures over a range of -0.4 to +30 ATM.	
Intended Use	The *Monarch™ COMPAK* Inflation Syringe is used to inflate and deflate balloon angioplasty catheters or other interventional devices, and to measure the pressure within the balloon during the procedure. It is also used to dispense fluids into the body and monitor the pressure of that fluid.	

Technological Characteristics	Technological characteristics of the subject *Monarch™ COMPAK* Inflation Syringe is equivalent to those of the predicate *Monarch™* Inflation Syringe [K011811]. This equivalence extends to the device's basic design, and function. Distinguishing differences do not raise any new questions regarding safety or efficacy of the device.
Safety & Performance Tests	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for this device. However, design verification testing was performed according to protocols based on the recommendations/ requirements of applicable FDA guidance and FDA recognized international standards. Verification testing, determined to be applicable to the safety and efficacy of the device, was shown to meet predetermined acceptance criteria. Biocompatibility requirements of ISO 10993-1:2003 *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing* and the FDA Modified ISO 10993 Test Profile for externally communicating, indirect blood contacting, limited-exposure devices have been met. Risk management, including a failure modes and effects analysis (FMEA), of the subject device was conducted. Subject product testing, based on conclusions from the FMEA, has yielded acceptable safety and performance outcomes in accordance with Merit internal protocols.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject *Monarch™ COMPAK* Inflation Syringe meets the requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, sterilization, principles of operation and indications for use to Merit's current commercially available *Monarch™* inflation syringe and *Viceroy™* Inflation syringe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Merit Medical Systems Inc.
c/o Ms. Susan D. Scott
Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K083523
Trade/Device Name: Monarch Compak Inflation Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: injector and syringe, angiographic
Regulatory Class: Class II
Product Code: DXT, MAV
Dated: January 5, 2009
Received: January 6, 2009

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K083523

Device Name: *Monarch™ COMPAK* Inflation Syringe &
Universal Fluid Dispensing Syringe

Indications for Use:

The *Monarch™ COMPAK* Inflation Syringe is used to inflate and deflate balloon angioplasty catheters or other interventional devices, and to measure the pressure within the balloon during the procedure. It is also used to dispense fluids into the body and monitor the pressure of that fluid.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR §801 Subpart D) (21 CFR §801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Chan

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083523