



Food and Drug Administration
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July 29, 2016

Merit Medical Systems, Inc.
Dan W. Lindsay
Project Manager, Regulatory Affairs
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K160107

Trade/Device Name: DiamondTOUCH Inflation Device and Fluid Dispensing Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT, MAV
Dated: June 27, 2016
Received: June 28, 2016

Dear Dan Lindsay:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Brian D. Pullin -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K160107

Device Name

DiamondTOUCH™ Inflation Device and Fluid Dispensing Syringe

Indications for Use (Describe)

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K160107

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	801-208-4408
	Fax Number:	801-253-6945
	Contact Person:	Dan W. Lindsay
	Date Prepared:	January 15, 2016
	Registration Number:	1721504

Subject Device	Trade Name:	DiamondTOUCH™ Inflation Device and Fluid Dispensing Syringe
	Common/Usual Name:	Inflation Syringe
	Classification Name:	Angiographic injector and syringe
	Regulatory Class:	Class II
	Product Code:	DXT
	Subsequent Product Code:	MAV
	21 CFR §:	870.1650
Review Panel:	74 Cardiovascular	

Predicate Device	Trade Name:	Monarch Inflation Syringe; Universal Fluid Dispensing Syringe
	Classification Name:	Injector and Syringe, Angiographic (DXT)
	Subsequent Classification Name:	Syringe, Balloon Inflation (MAV)
	Premarket Notification:	K011811
	Manufacturer:	Merit Medical Systems, Inc.

This predicate has not been subject to a design-related recall

Reference Devices	Trade Name:	basixTOUCH
	Classification Name:	Syringe, Balloon Inflation (MAV)
	Premarket Notification:	K130566
	Manufacturer:	Merit Medical Systems, Inc.

	Trade Name:	Monarch COMPAK Inflation Syringe and Universal Fluid Dispensing Syringe
	Classification Name:	Injector and Syringe, Angiographic (DXT)
	Premarket Notification:	K083523
	Manufacturer:	Merit Medical Systems, Inc.

Device Description	The DiamondTOUCH™ Inflation Device and Fluid Dispensing Syringe by Merit Medical is a 30mL disposable device with an integral pressure transducer, microcomputer, back-lit LCD, threaded plunger assembly with lock/release bar, a flexible high pressure extension tube, and a three-way stopcock. The DiamondTOUCH™ is designed to generate positive and negative pressure, and monitor positive pressures over a range of -0.4 ATM/BAR to +35ATM/BAR (-6 PSI to 514 PSI).
Indications for Use	The DiamondTOUCH Inflation Syringe is used to inflate and deflate balloon angioplasty catheters or other interventional devices and to measure the pressure and time of inflation within the balloon during the procedure. It is also used to dispense fluids into the body and monitor the pressure of that fluid.
Comparison to Predicate Device	<p>At a high level, the subject and predicate devices are based on the following same technological elements:</p> <ul style="list-style-type: none">• Same basic design with the same principle of operation.• Manual operated by manipulation of a rotating handle.• The plunger threads of both syringes can be locked or retracted by using the trigger of the handle. This action allows the plungers to be advanced or withdrawn or locked within the barrel.• When the trigger is released, the syringes both generate pressure by rotating the handle with the same clockwise motion.• Digital gauge that presents pressure and time of inflation. <p>The following technological differences exist between the subject and predicate devices:</p> <ul style="list-style-type: none">• The subject device has a larger volume (30ml verses 20ml).• The subject device has a higher pressure capability (35 ATM verses 30 ATM).• The digital display is larger with a visual representation of during inflation like an analog needle gauge.• The handle design was revised to incorporate a one handed preparation capability.
Performance Data	<p>No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject DiamondTOUCH Inflation Syringe was conducted based on the risk analysis and based on the requirements of the following international standards:</p> <ul style="list-style-type: none">• AAMI ANSI ES 60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment: Part I: General Requirements for basic safety and essential performance (19-5)

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- IEC 60601-1-2 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests (19-1)
 - IEC 62366:2008+A1: 2015 Medical devices - Application of usability engineering to medical devices (5-95)
 - IEC 60601-1-6 Edition 3.1:2012 Medical electrical equipment: Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability (5-89)
 - ISO 10993-1: 2009 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1. (2-156)
 - AAMI / ANSI / ISO 10993-5:2009/(R) 2014, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (2-153)
 - ISO 594-2 Second edition 1998-09-01 Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings (6-129)

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the DiamondTOUCH Inflation Syringe was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. As a result of the evaluation, a Cytotoxicity test was performed.

The DiamondTOUCH Inflation Syringe is considered an externally communicating device with indirect blood contact for a limited (≤ 24 hours) duration.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the DiamondTOUCH Inflation Syringe, consisting of the digital gauge. The system complies with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Performance Data cont.	Performance Testing	<ul style="list-style-type: none">• Accuracy Test• Tubing Tensile Retention• Display Functionality• Battery Life
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject DiamondTOUCH Inflation Syringe meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Monarch Inflation Syringe; Universal Fluid Dispensing Syringe, K011811.	
