



Food and Drug Administration
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January 20, 2016

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

Re: K153672
Trade/Device Name: basixTOUCH40 Inflation Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: MAV
Dated: December 18, 2015
Received: December 21, 2015

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,

Kenneth J. Cavanaugh -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)

K153672

Device Name

basixTOUCH40 Inflation Syringe

Indications for Use (Describe)

The basixTOUCH40 Inflation Syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.

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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5.0 510(k) Summary

| | | |
|---------------------------|----------------------|---|
| 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: | December 18, 2015 |
| | Registration Number: | 1721504 |

| | | |
|-----------------------|----------------------|-----------------------------------|
| Subject Device | Trade Name: | basixTOUCH40 Inflation Syringe |
| | Common/Usual Name: | Inflation Syringe |
| | Classification Name: | Angiographic injector and syringe |
| | Regulatory Class: | Class II |
| | Product Code: | MAV |
| | 21 CFR §: | 870.1650 |
| | Review Panel: | 74 Cardiovascular |

| | | |
|-------------------------|-------------------------|-----------------------------------|
| Predicate Device | Trade Name: | BasixTOUCH Inflation Syringe |
| | Classification Name: | Angiographic injector and syringe |
| | Premarket Notification: | K130566 |
| | Manufacturer: | Merit Medical Systems, Inc. |

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

| | |
|---------------------------|--|
| Device Description | The basixTOUCH40™ Inflation Syringe by Merit Medical is a 30mL disposable device with a threaded plunger assembly, a flexible high pressure extension tube. The basixTOUCH40™ is designed to generate positive and negative pressure, and monitor positive pressures over a range of zero to +40ATM/BAR (zero to 588 PSI). |
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| Indications for Use | <p>The basixTOUCH40 Inflation Syringe is used to inflate and deflate an angioplasty balloon or other interventional device, and to measure the pressure within the balloon.</p> <p>There is no change in the Indications for Use Statement from the predicate to the subject device.</p> |
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**Comparison to
Predicate
Device**

The Technological characteristics of the subject basixTOUCH40 inflation syringe are considerably equivalent to those of the predicate, the Merit BasixTOUCH Inflation Syringe. The basixTOUCH40 generates higher pressure than the Predicate. Specifically, the predicate maximum pressure is 35 ATM while the subject maximum pressure is 40 ATM.

The connection between the gauge and the syringe barrel was modified from a brass-fit connection to a snap-fit connection. The predicate used brass and adhesive to attach the gauge to the syringe barrel; the subject device uses a plastic molded component and o-ring to connect the gauge to the syringe barrel.

**Performance
Data**

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject basixTOUCH40 Inflation Syringe was conducted based on the risk analysis. The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Based on the categorization of the device with regard to patient contact and duration, biocompatibility testing is not required. Devices that do not have patient contact are not included in the scope of ISO 10993-1:2009, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process and FDA guidance Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May 1, 1995 (FDA Bluebook Memo G95-1).

Performance Testing

- Fluid Functional Use
- Vertical Gauge Tensile
- Horizontal Gauge Tensile
- Vacuum Capability
- Gauge Accuracy
- Retainer Cap Bond Torque
- Tip Adapter Securement and Tip Securement

The results of the testing demonstrated that the subject basixTOUCH40 Inflation Syringe met the predetermined acceptance criteria applicable to the safety and effectiveness of the device.

**Summary of
Substantial
Equivalence**

Based on the indications for use, design, safety and performance testing, the subject basixTOUCH40 Inflation Syringe meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the BasixTOUCH Inflation Syringe, K130566 manufactured by Merit Medical Systems, Inc.
