



Food and Drug Administration
10903 New Hampshire Avenue
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April 13, 2016

Medtronic, Inc.
Nisarg Shah
Regulatory Affairs Specialist
37a Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K153038

Trade/Device Name: Everest 20 Disposable Inflation Device, Everest 20 Survival Kit,
Everest 30 Disposable Inflation Device, Everest 30 Survival Kit

Regulation Number: 21 CFR 870.1650

Regulation Name: Angiographic Injector And Syringe

Regulatory Class: Class II

Product Code: MAV

Dated: March 11, 2016

Received: March 14, 2016

Dear Nisarg Shah:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K153038

Device Name

Medtronic's Everest™ Inflation Devices

Indications for Use (Describe)

The Everest 20cc Inflation Device/ Survival Kit is to be used to facilitate the use of catheters and guide wires during interventional procedures. The Everest 20cc Inflation Device is designed to be used to inflate/ deflate balloon catheters as well as to monitor pressure within the balloon. The Y/Tri-Adaptor with Hemostasis Valve is designed to be used on a guiding catheter or dilatation catheter to control backbleeding and to provide a port for introduction of fluids into the interventional system. The Guide Wire Insertion Tool is designed to facilitate placement of a guide wire tip through the Y/Tri-Adapter and into the wire lumen of an interventional catheter. The Guide Wire Steering Handle is designed to hold a small diameter guide wire and provide a handle for manipulating the wire.

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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Special 510(k) Summary

Submitter: **Medtronic Vascular**
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Date Prepared: March 11, 2016

**Device Trade Name
& Model Numbers:**

Trade Name	Model Number
Everest™ 20 Inflation Device	AC2200
Everest™ 20 Survival Kit	AC2205P
Everest™ 30 Inflation Device	AC3200
Everest™ 30 Survival Kit	AC3205P

Common Name: Syringe, Balloon Inflation

**Classification
Name:** Angiographic injector and syringe
Class II per 21 CFR §870.1650
Product Code: MAV

Predicate Device: The following Medtronic Everest™ Inflation Devices legally marketed currently were used as predicate devices in this 510(k) premarket notification:

1. **K942269** (Medtronic Everest™ 20 Inflation Device)
2. **K960983** (Medtronic Everest™ 30 Inflation Device, Survival Kit)

**Device
Description:** Medtronic's Everest™ Disposable Inflation Device is a sterile 20cc inflation device with a locking mechanism that is operated via a trigger. Normally, the locking mechanism is engaged. Once the trigger is pulled back, the locking mechanism is released and the piston can be manually manipulated.

The Everest™ 20 Device is outfitted with a manometer with measuring pressures ranging from vacuum to 20 bars in 0.5bar increments. The Everest™ 30 Device is outfitted with a

manometer with measuring pressure reading from vacuum to 30bars in 1 bar increments. A high pressure connecting tube with a male rotating adapter and a disposable 3-way stopcock are also included to aid in preparation of the device. When purchased as a “Survival Kit”, the package includes a Y-/ Tri-Adapter with hemostasis valve, a Guide Wire Insertion Tool and a Steering Handle.

Statement of Intended Use:

The Everest 20cc Inflation Device/ Survival Kit is to be used to facilitate the use of catheters and guide wires during interventional procedures. The Everest 20cc Inflation Device is designed to be used to inflate/ deflate balloon catheters as well as to monitor pressure within the balloon. The Y/Tri-Adaptor with Hemostasis Valve is designed to be used on a guiding catheter or dilatation catheter to control backbleeding and to provide a port for introduction of fluids into the interventional system. The Guide Wire Insertion Tool is designed to facilitate placement of a guide wire tip through the Y/Tri-Adapter and into the wire lumen of an interventional catheter. The Guide Wire Steering Handle is designed to hold a small diameter guide wire and provide a handle for manipulating the wire.

Summary of Technological Characteristics:

Medtronic’s Everest™ Disposable Inflation Device is a sterile 20cc inflation device designed to be used during interventional procedures to inflate/ deflate balloon catheters as well as monitor pressure within the balloon. Medtronic offers the Everest™ Inflation Device with a 20 atm or 30 atm pressure gauge. The Everest™ Inflation Device is constructed of the following key design components:

1. Syringe body with 20cc capacity
2. Body cap
3. Compression spring
4. Piston or lead screw
5. Half nut assembly
6. Rubber Plunger Tip
7. Plunger Insert
8. Gauge or Manometer (20 atm or 30atm)
9. High pressure tube with a male rotating adaptor
10. Trigger

The difference between the subject and predicate devices is the change in material of the rubber plunger tip component.

Summary of Non-

The device performance testing and biocompatibility testing

clinical Data: were performed in accordance to the relevant FDA guidance in order to demonstrate substantial equivalence to the legally marketed predicate devices.

Performance/ Bench Testing: The following tests performance or functional tests were performed to demonstrate substantial equivalence to the predicate devices:

1. Lubrication break away test
2. Pressurization test
3. Rubber Tip and Insert Tensile test
4. Compatibility with Contrast Media, Saline or any combination.

Biocompatibility testing: The Biocompatibility testing was performed pursuant to the requirements of ISO 10993-1: *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process.*

Based on the results of the Performance testing and Biocompatibility testing, no new concerns of safety and effectiveness were raised for Medtronic's Everest™ Inflation Devices. The test data demonstrate that the modified Everest™ Inflation Device is safe, effective, and performs as well or better than the predicate devices.

Summary of Clinical Data: No clinical investigations have been performed on the modified device.

Conclusion from Data: Medtronic Vascular has demonstrated that the modified Everest™ Inflation Devices are substantially equivalent to the legally marketed predicate devices based on the intended use and technological characteristics.