April 13, 2022

Medtronic Vascular
Nikita Ciandra Vaz
Senior Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K220773
Trade/Device Name: Everest 20 Inflation Device; Everest 30 Inflation Device; Everest 20 Survival Kit; 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 15, 2022
Received: March 16, 2022

Dear Nikita Ciandra Vaz:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220773

Device Name
Everest™ 20 Inflation Device; Everest™ 20 Survival Kit
Everest™ 30 Inflation Device; Everest™ 30 Survival Kit

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-Adapter 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.

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Special 510(k) Summary

Submitter: **Medtronic Vascular**
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Submission Number: K220773

Date Prepared: March 15, 2022

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 are used as predicate devices in this 510(k) premarket notification:

K153038 (Medtronic Everest 20 Disposable Inflation Device, Everest 20 Survival Kit, Everest 30 Disposable Inflation Device, Everest 30 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 30 bars 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-Adapter 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 (20 atm or 30 atm)
9. High pressure tube with a male rotating adaptor
10. Trigger

The subject device (Everest™ Disposable Inflation Device) has the same technological characteristics as that of the predicate device, including the same design, material, chemical composition, principle of operation, and performance specifications.

Comparison to the predicate device:

The following information outlines the differences and similarities between the subject device and the predicate device:

- Similar Intended Use/ Indication for Use
- Similar Technological characteristics
- Similar Device design, materials, principle of operation
- Similar packaging
- Similar sterilization technology/ method
- Different labeling

The differences in labeling include the following:

- Addition of a symbol that implies 'Single sterile barrier system with protective packaging outside' (per ISO 15223-1 standard).
- Updated the Instructions for Use (IFU) document to describe the symbol mentioned above.
- Addition of a yellow label on the outer bag, providing clarity to the end user about the single sterile barrier packaging configuration.

Medtronic's modified Everest™ Disposable Inflation Device is substantially equivalent to

	the predicate device based on similarities in intended use and technological characteristics. The testing performed to assess safety and effectiveness demonstrated that the modified device does not raise any new concerns of safety and effectiveness.
Summary of Non-clinical Data:	The following testing was performed to assess safety and effectiveness of Medtronic's modified Everest™ Inflation Devices: I) Packaging Performance Testing 1) Visual Inspection of Seals 2) Labeling Legibility and Adhesion 3) Seal Strength 4) Sterile Barrier Integrity Bubble Leak 5) Minimum Seal Width 6) Peel-Open/ Aseptic Presentation 7) IFU Legibility Test II) Package Shelf-Life Testing 1) Visual Inspection of Seals 2) Labeling Legibility and Adhesion 3) Seal Strength 4) Sterile Barrier Integrity Bubble Leak 5) Minimum Seal Width 6) Peel-Open/ Aseptic Presentation 7) IFU Legibility Test No new safety or effectiveness issues were raised during the testing. The test data demonstrated that the modified Medtronic's Everest™ Inflation Devices is as safe and effective as the legally marketed predicate device.
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.