



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

August 7, 2015

Medtronic, Inc.  
c/o Mark Job  
Regulatory Technology Services LLC  
1394 25th Street NW  
Buffalo, MN 55313

Re: K152054  
Trade/Device Name: Confida Adaptive Sheath  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter Introducer  
Regulatory Class: II  
Product Code: DYB  
Dated: July 23, 2015  
Received: July 23, 2015

Dear Mark Job:

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. 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" (21CFR 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,

**Bram D. Zuckerman -S**

Bram Zuckerman, MD  
Director  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

Device Name

Confida™ Adaptive Sheath

Indications for Use (Describe)

The Confida™ Adaptive Sheath is intended to provide a conduit through the iliofemoral vessels for the insertion of diagnostic or interventional devices used during cardiovascular procedures, including transcatheter aortic valve replacement (TAVR).

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary

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As required by the Safe Medical Devices Act of 1990, coded under Section 513, part (1)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

**Date Prepared:** April 13, 2015

**Applicant/  
Submitter:** **Medtronic, Inc.**  
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Minneapolis, MN 55432  
USA  
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**Contact Person:** **Matthew Lobeck**  
Regulatory Affairs Specialist  
Medtronic Heart Valves  
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**Device Trade Name:** Confida™ Adaptive Sheath

**Model Number:** CAS131830

**Device Common  
Name:** Confida Sheath

**Classification Name:** Catheter Introducer

**Classification:** Class II, 21 CFR 870.1340

**Product Code:** DYB

**Predicate Devices:**

- Primary Predicate Device: Medtronic Sentrant Introducer Sheath with Hydrophilic Coating (K123990, cleared April 26, 2013)
- Secondary Predicate Device: Edwards eSheath Introducer Set (K141696, cleared September 18, 2014)

**Device Description:** The Confida™ Adaptive Sheath is a single-use, disposable, hydrophilically-coated sheath designed to provide a flexible and hemostatic conduit for the insertion of diagnostic and interventional devices, including devices used in transcatheter aortic valve replacement (TAVR). The Confida™ Adaptive Sheath is a prescription use device, intended to be used by professionals in healthcare/hospital facilities. There is only one model of the Confida™ Adaptive Sheath, corresponding to model number CAS131830.

The Confida™ Adaptive Sheath is comprised of two components:

- **Dilator component:** The Dilator component includes a flexible, tapered distal tip that facilitates atraumatic tracking through the vasculature. The Dilator component contains an internal lumen able to accommodate up to a 0.035in (0.89mm) guidewire.
- **Introducer Sheath component:** A hydrophilic coating is applied to the sheath body to reduce the forces required for insertion into and withdrawal from the vasculature. The seal housing contains a hemostatic valve assembly designed to minimize blood loss during device use. The Introducer Sheath component contains a sideport extension with a three-way valve, providing a means for fluid to be flushed through the Introducer Sheath component during clinical use.

The sheath body temporarily expands in diameter to allow the introduction and removal of devices up to 18 Fr in outer diameter, including devices used in TAVR procedures.

There are no specific accessories required for use with the Confida™ Adaptive Sheath. The Confida™ Adaptive Sheath is designed for use with guidewires up to 0.035in (.89mm) in diameter, and has been developed for use with various devices used in diagnostic and interventional procedures, including TAVR procedures.

The Confida™ Adaptive Sheath is classified as a surgically invasive device for short-term use (<24 hours) contacting circulatory blood, per ISO 10993-1:2009. The Confida™ Adaptive Sheath is sterilized by Ethylene Oxide (EtO) to a minimum sterility assurance level (SAL) of 10<sup>-6</sup>.

**Statement of Intended Use:**

The Confida™ Adaptive Sheath is intended to provide a conduit for the insertion of diagnostic and interventional devices into the vasculature and minimize blood loss associated with such insertions.

**Statement of Indications for Use:**

The Confida™ Adaptive Sheath is intended to provide a conduit through the iliofemoral vessels for the insertion of diagnostic or interventional devices used during cardiovascular procedures, including transcatheter aortic valve replacement (TAVR).

**Comparison of Indications for Use to Predicate Devices:**

The Indications for Use of the Confida™ Adaptive Sheath are within the scope of the Indications for Use of both predicate devices. While differences exist between the Indications for Use of the subject and predicate devices, these differences do not raise any new issues of safety and effectiveness of the subject device; nor do these differences result in a subject device intended use that differs significantly from the intended use of the predicate devices.

**Contraindications:**

The Confida™ Adaptive Sheath is contraindicated for unheparinized patients and patients presenting with an intolerance to anticoagulation therapy.

**Comparison of Technological Characteristics to Predicate Device(s):**

The Confida™ Adaptive Sheath has the following similarities to the predicate devices:

- Intended Use (all predicates)
- Indications for Use (all predicates)
- Target population (all predicates)
- Fundamental scientific technology (all predicates)
- Operating principle (all predicates)
- Expandability (secondary predicate)
- Guidewire compatibility (all predicates)
- Hemostasis technology (all predicates)
- Packaging Materials (primary predicate)
- Sterility Assurance Level (all predicates)
- Method of sterilization (secondary predicate)

The following technological characteristics of the Confida™ Adaptive Sheath differ from the predicate devices:

- Device working length
- Device materials

**Summary of Non-Clinical Data:**

In order to demonstrate substantial equivalence of the subject device (Confida™ Adaptive Sheath) to the predicate devices, the following non-clinical evaluations were performed:

- System Pressure Capability: Leak and Hemostasis Testing
- Dimensional Measurement Testing
- Tensile Strength Testing
- Coating Integrity
- Particulate Testing
- Kink Resistance Testing
- Device and Delivery System Interaction Forces Testing
- Simulated Use: System Recovery and Device Functionality Testing
- Usability Testing for Design Validation
- *In Vivo* Design Validation Testing in an Animal Model

Biocompatibility testing was also performed on the Confida™ Adaptive Sheath per the requirements of ISO 10993-1: 2009, as listed below:

- Cytotoxicity Study using the ISO MEM Elution Method
- ISO Sensitization (Maximization Method)
- ISO Intracutaneous Reactivity
- ISO Systemic Toxicity
- Material Mediated Pyrogen Study
- ASTM Hemolysis Study
- ASTM Partial Thromboplastin Time (PTT) Coagulation Testing
- C3a and SC5b-9 Complement Activation Testing
- Thromboresistance

- Chemical Characterization Testing

In addition, sterilization validation, packaging, and shelf life testing (product and package) was performed on the Confida™ Adaptive Sheath.

The results of the non-clinical testing performed for the Confida™ Adaptive Sheath show that all acceptance criteria were met. The non-clinical evaluations verify the Confida™ Adaptive Sheath is substantially equivalent to the predicate devices and is adequate for its intended use.

**Conclusion:**

Based on the information above, the Confida™ Adaptive Sheath is substantially equivalent in intended use, performance, and fundamental scientific technology to the predicate devices, the Medtronic Sentrant Introducer Sheath with Hydrophilic Coating (K123990) and the Edwards eSheath Introducer Set (K141696).