December 20, 2017

Medtronic Vascular, Inc.
Wee Wen Leow
Senior Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, California 95403

Re: K171866
Trade/Device Name: Sentrant Introducer Sheath with Hydrophilic Coating
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 20, 2017
Received: November 21, 2017

Dear Wee Wen Leow:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171866

Device Name
Sentrant Introducer Sheath with Hydrophilic Coating

Indications for Use *(Describe)*
The Sentrant Introducer Sheath with Hydrophilic Coating is intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and minimize blood loss associated with such insertions.

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 - K171866

Submitter:	Medtronic Vascular, Inc. 3576 Unocal Place Santa Rosa, CA 95403 (707) 591-2091 (707) 566-1432
Contact Person:	Wee Wen Leow Sr. Regulatory Affairs Specialist 3576 Unocal Place Santa Rosa, CA 95403 (707) 543-5043 (707) 566-1245 wee.wen.leow@medtronic.com
Date Prepared:	June 21, 2017
Device Trade Name:	Sentrant™ Introducer Sheath with Hydrophilic Coating
Device Classification:	Class II
Classification Name:	Catheter Introducer
Regulation Number:	21 CFR 870.1340
Classification Product Code:	DYB
Classification Panel:	Cardiovascular
Predicate Device:	Sentrant Introducer Sheath with Hydrophilic Coating (K123990)

Device Description:

The Sentrant Introducer Sheath is a single-use, disposable, hydrophilic-coated catheter designed to provide a flexible and hemostatic conduit for the insertion of endovascular devices and to minimize blood loss associated with vascular procedures. The system is comprised of a dilator and an introducer sheath. The system accommodates a 0.035 in (0.89 mm) guidewire and is available in 28 and 64 cm lengths and in sizes from 12 to 26 Fr in 2 French increments.

The dilator is radiopaque and has a flexible tapered tip that facilitates atraumatic tracking through the vasculature. There is a dilator grip at the proximal end of the dilator shaft. The dilator grip has a female Luer taper fitting on the proximal end to allow flushing of the device, and a threaded-feature at the distal end to allow the dilator to be secured to the sheath seal housing (dilator locking mechanism).

The introducer sheath is comprised of a hydrophilic-coated, coil-reinforced catheter that is attached to a rigid seal housing containing the hemostatic valve assembly. A sideport extension assembly with a 3-way valve is attached to the seal housing. A radiopaque (RO) marker band is located at the distal tip of the sheath. The device also has a suture loop for attaching it to the patient and a strain relief to minimize kinking of the catheter where it joins to the seal housing.

Intended Use:

The Sentrant Introducer Sheath with Hydrophilic Coating is intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and minimize blood loss associated with such insertions.

Comparison of Technical Characteristics:

The Sentrant Introducer Sheath with Hydrophilic Coating, sterilized via Ethylene Oxide, has the same fundamental technological characteristics as the predicate device, Sentrant Introducer Sheath with Hydrophilic Coating, sterilized via E-beam irradiation. The form, fit, function, and principles of operation are the same.

Description	Predicate Device (K123990)	Subject Device (in comparison with predicate)
Condition of Use	Single use	Same
Sheath Diameters	12 Fr to 26 Fr (2 Fr increments)	Same
Sheath Working Length	28 cm 64 cm	Same
Guidewire Compatibility	0.035”	Same
Hydrophilic Coating	Yes	Same
Radiopacity	Dilator- fully radiopaque Sheath - marker band at tip	Same
Hemostasis Technology	Silicone Seals	Same
Device Materials	Dilator: HDPE or HDPE/LDPE Blend, BaSO4	Same

Description	Predicate Device (K123990)	Subject Device (in comparison with predicate)
	Sheath: Composite structure composed of HDPE, Orevac and Pebax with an encapsulated stainless steel coil	
Sterility	Sterile to the SAL of 10^{-6}	Same
Sterilization Method	E-beam	Ethylene Oxide
Shelf Life	1 year	2 years

Substantial Equivalence to K123990:

The assessment of non-clinical performance data demonstrates that the Sentrant Introducer Sheath with Hydrophilic Coating, sterilized via Ethylene Oxide (EtO), is substantially equivalent to the Sentrant Introducer Sheath with Hydrophilic Coating, sterilized via E-beam irradiation.

Non-Clinical Performance Data:

The following tests were performed on the subject device to demonstrate that the device meets performance requirements for its intended use. All the predetermined acceptance criteria were met and results passed to support a determination of substantial equivalence.

- Design Verification Testing
- Sterilization Validation per requirements of ISO 11135
- Biocompatibility Testing per the requirements of ISO 10993-1
- Packaging Design Verification Testing per requirements of ISO 11607-1
- Shelf Life Testing

Conclusion:

The Sentrant Introducer Sheath with Hydrophilic Coating, sterilized via Ethylene Oxide (EtO), is substantially equivalent in intended use, technological characteristics, and performance to the previously cleared Sentrant Introducer Sheath (K123990). The subject device has the same fundamental technological characteristics, principles of operation, and applications as the predicate device.