DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

May 30, 2017

AngioDynamics, Inc.
Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlboro, MA 01752

Re: K170695
Trade/Device Name: VenaCure EVLT NeverTouch Direct Introducer Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 28, 2017
Received: March 7, 2017

Dear Robin Fuller:

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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*

K170695

Device Name
VenaCure EVLT NeverTouch Direct Introducer Sheath

Indications for Use *(Describe)*
The VenaCure EVLT NeverTouch Introducer Sheath is indicated for use with VenaCure EVLT NeverTouch Direct Kit to introduce the laser fiber into the peripheral vasculature

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 FOR THE
ANGIODYNAMICS, INC. VENACURE EVLT NEVERTOUCH INTRODUCER SHEATH

Date Prepared: 25-May-2017

A. Sponsor:

AngioDynamics, Inc.
26 Forest Street
Marlborough, MA 01752

B. **Contact:**

Robin Fuller
Sr. Manager Regulatory Affairs
Tel: 508-658-7986
Fax: 508-658-7976
Email: RFuller@angiodynamics.com

C. Subject Device:

Trade Name:	AngioDynamics VenaCure EVLT NeverTouch Direct Introducer Sheath
Common Name:	Catheter Introducer
Regulation Number;	21 CFR 870.1340
Regulation Name:	Introducer Catheter
Regulatory Class:	Class II
Product Code:	DYB
Classification Panel:	Cardiovascular

D. **Predicate Device:**

Trade Name:	Hemostasis Valve Catheter Introducer
510(k) Reference:	K043525
Common Name:	Catheter Introducer
Regulation Number;	21 CFR 870.1340
Regulation Name:	Introducer Catheter
Regulatory Class:	Class II
Product Code:	DYB
Classification Panel:	Cardiovascular

E. Device Description:

The proposed VenaCure EVLT NeverTouch Direct Introducer Sheath is currently provided in the VenaCure EVLT NeverTouch Direct Procedure Kits as a kit accessory as a legally marketed device covered under the manufacturers 510(k). The kit consists of a laser fiber, introducer sheath, entry needle, and a guidewire. The VenaCure EVLT NeverTouch Direct Procedure kit is used to treat patients with varicose veins via endovascular coagulation by dispersing energy from a diode laser directly into the vein being treated. The Introducer Sheath is used to introduce the laser fiber into the vein.

F. Intended Use/Indications for Use:

The VenaCure EVLT NeverTouch Direct Introducer Sheath is intended for use with the VenaCure EVLT NeverTouch Direct Procedure kit. to introduce the laser fiber into the peripheral vasculature.

The predicate device is indicated for use in percutaneous procedures to introduce catheters and other intravascular devices into the peripheral vasculature.

The slight differences in indications between the proposed and predicate device do not affect the intended therapeutic or surgical use of the device. Both are indicated for introducing intravascular devices into the peripheral vasculature, the proposed device is just specific to introduction of the laser fiber. Therefore, there is no effect on the safety and effectiveness of the device when used as labeled.

G. Summary of Similarities and Differences in Technology Characteristics and Performance:

The proposed device has the identical design and technical characteristics as the predicate device. The purpose of this 510(k) submission is to introduce into commercial distribution a sterile, single packaged VenaCure EVLT NeverTouch Direct Introducer Sheath. The proposed VenaCure EVLT NeverTouch Direct Introducer Sheath is currently provided in the VenaCure EVLT NeverTouch Direct Procedure Kits

H. Performance Data:

The performance testing included non-clinical bench testing. The following tests were performed.

- Sheath Dimensional Testing
- Dilator Dimensional Testing
- Luer Fitting ISO Compliance

- Tensile Testing
- Sheath Leakage
- Hemostasis Valve Leakage
- Biocompatibility per ISO 10993-1

This testing supports substantial equivalence of the proposed device to the predicate device as it confirms that both meet the same specifications.

The following standards were followed for the proposed device:

. BIOCOMPATIBILITY

- The proposed VenaCure EVLT NeverTouch Introducer Sheath conforms to the following FDA recognized standards:
  - AAMI/ANSI/ISO 10993-1: 2009(R)2013, Biological evaluation of medical devices - Part 1: Evaluation and Testing Within a Risk Management Process
  - ANSI/AAMI/ISO 10993-4: 2002(R)/2013 & A1:2006(R) 2013, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
  - AAMI/ANSI/ISO 10993-5: 2009(R)2014, Biological evaluation of medical devices - Part 5: Tests for In-Vitro cytotoxicity
  - AAMI/ANSI/ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
  - AAMI/ANSI/ISO 10993-11:2006/(R)2010, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
  - AAMI/ANSI/ISO 10993-12: 2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
  - USP 37-NF-32<151>2014, Pyrogen Test

STERILIZATION/MICROBIOLOGICAL

- The proposed VenaCure EVLT NeverTouch Introducer Sheath conforms to the following FDA *recognized* standards:
  - AAMI/ANSI/ISO 10993-7: 2008/(R) 2012, Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals
  - AAMI/ANSI/ISO 11135: 2014 Sterilization of Health Care Products – Ethylene Oxide – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
  - AAMI/ANSI/ISO 11138-1: 2006/ (R) 2010 Sterilization of Health Care Products; Biological Indicators – Part 1: General Requirements
  - AAMI/ANSI/ISO 11737-1:2006 (R) 2011, Sterilization of Medical Devices-Microbiological Methods- Part 1: Estimation of Population on Microorganisms on Product
  - AAMI ST72:2011 (2016), Bacterial Endotoxin – Test methodologies, routine monitoring and alternatives to batch testing

- The proposed VenaCure EVLT NeverTouch Introducer Sheath conforms to the following *voluntary* standards:
  - EN 556-1: 2001, Sterilization of Medical Devices: 'Requirements for medical devices to be labeled “sterile”-Part 1: Requirements for Terminally Sterilized Medical Devices

- AAMI/ANSI/ISO 11138-2: 2009 Sterilization of Health Care Products; Biological Indicators – Part 2: Biological Indicators of Ethylene Oxide Sterilization

PACKAGING

- The proposed VenaCure EVLT NeverTouch Introducer Sheath conforms to the following FDA *recognized* standards:
  - ISO 11607-1 First Edition, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
  - ISO 11607-2: 2006(R)2010, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes, 1ed
  - ASTM F 88: 2009, Standard Test Method for Seal Strength of Flexible Barrier Materials
  - ASTM F 1980-2016, Standard Guide for Accelerated Aging of Sterile Medical Device Packages
  - ASTM F 1929- 2015, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
  - ASTM F 1886: 2009(R)2013 Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
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I. Conclusion:

The results of the non-clinical testing and a discussion of the similarities between the proposed and predicate device demonstrate that the proposed and predicate devices are substantially equivalent.