



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

August 24, 2017

AngioDynamics, Inc.
Hans Kjolhede
Specialist I, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K171921

Trade/Device Name: VenaCure EVLT NeverTouch Procedure Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And
In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: June 26, 2017
Received: June 27, 2017

Dear Hans Kjolhede:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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

Indications for Use

510(k) Number (if known)

Device Name

VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits

Indications for Use (Describe)

The VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

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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**510(K) SUMMARY FOR THE
VENACURE EVLT TRE' SHEATH AND NEVERTOUCH PROCEDURE KITS**

Date prepared: 06/26/2017

A. Sponsor

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B. Contact

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Subject Device:

Trade Name:	VenaCure EVLT Tre' Sheath VenaCure EVLT NeverTouch Procedure Kit
Common Name:	Greater Saphenous Vein Procedure Kit
Regulation Number:	21 CFR 878.4810
Regulation Name:	Laser Instrument, Surgical Powered
Regulatory Class:	Class II
Product Code:	GEX
Classification Panel:	General Hospital & Plastic Surgery

Predicate Device

Trade Name:	AngioDynamics VenaCure EVLT Tre' Sheath And VenaCure EVLT NeverTouch Procedure Kit
510(k) Reference:	K162914
Common Name:	Grater Saphenous Vein Procedure Kit
Regulation Number:	21 CFR 878.4810
Regulation Name:	Laser Instrument, Surgical Powered
Regulatory Class:	Class II
Product Code:	GEX
Classification Panel:	General Hospital & Plastic Surgery

C. Device Description

The VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits include a variety of procedural accessories:

- NeverTouch Fiber with Sheath-Loc Fitting
- Tre' Sheath Introducer with Dilator
- Teflon Coated Stainless Steel Guidewire (lengths from 70cm to 200cm)
- 0.018 Guidewire (Lengths from 45cm to 200cm)
- Micro Access Components:
 - 21 gauge Entry Needle
 - 5F x 10cm Sheath/Dilator
 - 0.018" x 45cm Guidewire
 - 19 gauge Entry Needle (optional)

The VenaCure EVLT Tre' Sheath is a 4F sheath used during endovascular venous laser treatment procedures. The sheath is used as a conduit for placing a laser fiber. The product will be offered in 25, 45, 65, and 90cm lengths. The VenaCure EVLT Tre' Sheath will be provided both as a standalone product and also packaged with the various procedural accessories detailed above.

D. Intended Use/Indications for Use

The VenaCure EVLT Tre' Sheath and VenaCure EVLT NeverTouch Procedure Kits are indicated for endovascular coagulation of the Great Saphenous Vein (GSV) in patients with superficial vein reflux, for the treatment of varicose veins and varicosities associated with superficial reflux of the Great Saphenous Vein (GSV), and for the treatment of incompetence and reflux of superficial veins of the lower extremity.

E. Technological Characteristics

The proposed device will now incorporate a blue silicone gasket lubricated with silicone into the Tre' Sheath Hemostasis Valve Assembly. Additionally, the housing of the Tre' Sheath Hemostasis Valve Female Luer and Tre' Sheath Hemostasis Valve Body will be altered to compensate for the addition of the silicone gasket. Indications for Use and all other technological characteristic will remain the same as the predicate.

F. Performance Data

The proposed VenaCure EVLT Tre' Sheath and VenaCure NeverTouch EVLT Procedure Kit are substantially equivalent to the specified predicate device based on a comparison of technological characteristics and the results of non-clinical performance and material testing, which include:

- Leak Resistance
- Tensile Strength
- Dilator Withdrawal Force
- Dilator Insertion
- Biocompatibility per ISO 10993-1

G. Conclusion

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