July 20, 2023

AngioDynamics, Inc.
Laura Dwyer
Regulatory Affairs Specialist
603 Queensbury
Queensbury, New York 12804

Re: K231945
Trade/Device Name: VenaCure EVLT NeverTouch Procedure Kits; VenaCure EVLT NeverTouch Direct Procedure Kits
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, DYB
Dated: June 29, 2023
Received: June 30, 2023

Dear Laura Dwyer:

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,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K231945

Device Name
VenaCure EVLT NeverTouch Procedure Kits and NeverTouch Direct Procedure Kits

Indications for Use *(Describe)*

VenaCure EVLT NeverTouch Procedure Kit:
"The AngioDynamics 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."

VenaCure EVLT NeverTouch Direct Introducer Sheath:
"The AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct Introducer Sheath is indicated for use with the VenaCure EVLT NeverTouch Direct Procedure Kit to introduce the laser fiber into the peripheral vasculature."

VenaCure EVLT NeverTouch Direct Procedure Kit
"The AngioDynamics, Inc. VenaCure EVLT NeverTouch Direct 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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FORM FDA 3881 (6/20) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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

A. SPONSOR

AngioDynamics, Inc.
26 Forest Street
Marlborough, MA 01752
USA

B. CONTACT

Laura Dwyer
Regulatory Affairs, Specialist I,
Tel: 508.658.7813
Email: laura.dwyer@angiodynamics.com

C. DEVICE NAME

Trade Name:	VenaCure EVLT NeverTouch Direct Procedure Kits VenaCure EVLT NeverTouch Procedure Kits
Common/Usual Name:	VenaCure EVLT NeverTouch Procedure Kit VenaCure EVLT NeverTouch Tre'Sheath VenaCure EVLT NeverTouch Direct Procedure Kits Venacure Evlt Nevertouch Direct Introducer Sheath
Classification Name:	Powered laser surgical instrument
Classification Panel:	General & Plastic Surgery (21 CFR § 878.4810, Class II, Pro-Code GEX)

D. PREDICATE DEVICE

510(k):	K171921
Trade Name:	Venacure EVLT Nevertouch Procedure Kit
Common/Usual Name:	VenaCure EVLT NeverTouch Procedure Kit VenaCure EVLT Tre'Sheath
Classification Name:	Powered laser surgical instrument
Classification Panel:	General & Plastic Surgery (21 CFR § 878.4810, Class II, Pro-Code GEX)

E. REFERENCE DEVICES

510(k):	K170695
Trade Name:	VenaCure EVLT NeverTouch Direct Introducer Sheath
Common/Usual Name:	VenaCure EVLT NeverTouch Direct Introducer Sheath
Classification Name:	Introducer, catheter
Classification Panel:	General & Plastic Surgery (21 CFR § 878.1340, Class II, Pro-Code DYB)

510(k):	K112600
Trade Name:	VenaCure EVLT NeverTouch Direct Procedure Kit
Common/Usual Name:	VenaCure EVLT NeverTouch Direct Procedure Kit VenaCure EVLT NeverTouch Direct Introducer Sheath
Classification Name:	Powered laser surgical instrument
Classification Panel:	General & Plastic Surgery (21 CFR § 878.4810, Class II, Pro-Code GEX)

E. DEVICE DESCRIPTION

VenaCure EVLT NeverTouch and NeverTouch Direct Fiber Procedure Kits should be used only with lasers cleared for use in the treatment of varicose veins, varicosities with superficial reflux of the GSV, and in the treatment of incompetent refluxing veins in the superficial venous system in the lower extremity.

VenaCure EVLT NeverTouch Procedure Kit

The VenaCure EVLT Fiber Procedure Kits include single use disposable devices for use with a laser for the treatment of varicose veins. In addition, the Trè-Sheath Introducer is available both in the kits and provided individually. The main components of the NeverTouch Procedure Kit are identified below:

- 600µ VenaCure EVLT NeverTouch Fiber
- 4Fr Tre' Sheath Introducer
- 0.035" Guidewire
- 19 Gauge or 21 Gauge Entry Needle

VenaCure EVLT NeverTouch Direct Fiber Procedure Kit

The VenaCure EVLT NeverTouch Direct Procedure Kits is comprised of single use disposable devices for use with a laser for the treatment of varicose veins. The VenaCure EVLT NeverTouch Direct Fiber Procedure Kits are comprised of

- 21 Gauge Entry Needle
- 0.018" Guidewire
- Introducer Sheath/Dilator Assembly
- Fiber

F. INDICATION FOR USE

VenaCure EVLT NeverTouch Procedure Kit & Tre' Sheath Set:

The VenaCure EVLT NeverTouch Procedure Kit is 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.

VenaCure EVLT NeverTouch Direct Procedure Kit:

The VenaCure EVLT NeverTouch Direct Procedure Kit is 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.

VenaCure EVLT NeverTouch Direct Introducer Sheath:

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

G. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The proposed VenaCure EVLT NeverTouch and NeverTouch Direct Procedure Kits and the predicate VenaCure EVLT NeverTouch and NeverTouch Direct Procedure Kits are identical to one another (and therefore substantially equivalent) in all aspects, not limited to design, materials, manufacturing, specifications, dimensions, and indication for use. The difference is the proposed VenaCure EVLT NeverTouch and NeverTouch Direct Procedure Kits is an update to the labeling.

H. DEVICE MODIFICATIONS AND RISKS ASSOCIATED WITH THE DESIGN MODIFICATION(S)

Modifications made to the VenaCure EVLT NeverTouch and NeverTouch Direct Procedure Kits were limited to updating the labeling.

There is no change to the principles of operation, indications for use, intended use, fundamental scientific technology, or technological characteristics between the proposed VenaCure EVLT NeverTouch and NeverTouch Direct Procedure Kits and the predicate/reference devices.

The impact of the changes as described within this submission were evaluated as part of the Risk Analysis activity in terms of new/existing risks and new/existing failure modes. The results of this Risk Analysis activity were compared to the current Risk Analysis; the conclusions drawn from this assessment, determined the proposed modifications did not impactor modify an existing risk nor necessitate a new or modified risk.

I. NON-CLINICAL TESTING

The proposed VenaCure EVLT NeverTouch Procedure Kits and NeverTouch Direct Procedure Kits and the predicate/reference devices have the same indications for use, intended use, principles of operation, and fundamental scientific technology. The labeling updates to the VenaCure EVLT NeverTouch Procedure Kits and NeverTouch Direct Procedure Kits do not affect the materials, design, biocompatibility/sterilization, technical characteristics, functionality, performance (bench), or usability therefore new testing was not conducted to support the change and previous testing was leveraged from the predicate (K171921) and reference devices (K170695 and K112600).

J. CONCLUSIONS

The proposed labeling change to the VenaCure EVLT NeverTouch Procedure Kits and NeverTouch Direct Procedure Kits does not change its intended use nor does it change the principles of operation.The proposed and predicate/reference devices are substantially equivalent.