AngioDynamics, Inc.
% Mr. Deepa Godhiya
Specialist, Global Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K181044
Trade/Device Name: 400µm Perforator and Accessory Vein Ablation Kit
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and n Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: April 17, 2018
Received: April 19, 2018

Dear Mr. Godhiya:

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 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,

Peter L. Hudson -S
2018.07.03 14:06:42 -04'00'

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: 06/30/2020
See PRA Statement below.

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

Device Name
400µm Perforator and Accessory Vein Ablation Kit

Indications for Use *(Describe)*
The 400µm Perforator and Accessory Vein Ablation Kit is intended for use in the treatment of superficial vein reflux of the greater saphenous vein associated with varicosities. The 400µm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for the treatment of incompetent (i.e. refluxing) perforator veins (IPVs).

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 – 400μM PERFORATOR AND ACCESSORY VEIN ABLATION KIT
Date Prepared: April 17, 2018

A. SPONSOR

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B. CONTACT

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C. DEVICE NAME

Trade Name:	400μm Perforator and Accessory Vein Ablation Kit
Common/Usual Name:	Laser Vein Ablation Procedure Kit
Classification Name:	Power Laser Surgical Instrument (ProCode: GEX)
Classification Panel:	General and Plastic Surgery

D. PREDICATE DEVICE(S)

510(k) Number	**K041957**
Trade Name:	AngioDynamics, Inc. (Diomed, Ltd.) EVLT Kit and the D15 Plus and D30 Plus Diode Lasers
Common/Usual Name:	Laser Vein Ablation Procedure Kit
Classification Name:	Power Laser Surgical Instrument (ProCode: GEX)
Classification Panel:	Dermatology and Plastic Surgery

510(k) Number	**K052003**
Trade Name:	VNUS RFS and VNUS RFS Flex
Common/Usual Name:	Bipolar Electrosurgical Instrument
Classification Name:	Electrosurgical, Cutting & Coagulation & Accessories (ProCode: GEI)
Classification Panel:	Dermatology and Plastic Surgery

E. DEVICE DESCRIPTION

The 400μm Perforator and Accessory Vein Ablation Kit is used to treat patients with varicose veins. Varicose veins are large, twisted, visibly bulging veins usually located in the legs. Varicose Veins occur when either the blood flow is too slow or valves are not functioning correctly resulting in "pile-up" of blood within the lower extremity veins. AngioDynamics proposes that this include the Incompetent Perforator Veins (IPVs). The 400μm Perforator and Accessory Vein Ablation Kit is provided in a procedure kit which includes a 400μm Fiber along with the following accessory components:

- 21G Entry Needle
- 4F Introducer Sheath/Dilator
- 0.018" Guidewire

The 400μm Perforator and Accessory Vein Ablation Kit is presented sterile and contains all of the accessories needed to perform the EVLT procedure, with the exception of generic disposable items routinely found in a well-equipped minor treatment room such as drapes, swabs, bandages etc.

F. INTENDED USE/INDICATIONS FOR USE

"*The 400μm Perforator and Accessory Vein Ablation Kit is indicated for use in the treatment of superficial vein reflux of greater saphenous vein associated with varicosities. The 400μm Perforator and Accessory Vein Ablation Kit is indicated for treatment of incompetence and reflux of superficial veins in the lower extremity, and for the treatment of Incompetent (i.e. refluxing) Perforator Veins (IPVs).*"

G. SUMMARY OF SIMILARITIES AND DIFFERENCES IN TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE

The proposed 400μm Perforator and Accessory Vein Ablation Kit is substantially equivalent to the predicate devices, both previously reviewed and cleared by the Agency, based upon the following conclusions:

- to **K041957** (EVLT Kit and the D15 Plus and D30 Plus Diode Lasers) in terms of overall design, materials, kitted accessories, labeling, and other design-related attributes - please refer to the table below for a side-by-side comparison of the Kit Accessories of the proposed device to that cleared via this predicate 510(k),

Proposed Kit	Predicate Kit (K041957)
21G Entry Needle	19G Entry Needle
0.018" Guidewire	0.035" Guidewire
4F Introducer Sheath/Dilator	4F & 5F Introducer Sheath/Dilator

- to **K052003** (VNUS RFS and RFS Flex Devices) in regards to the Indications for Use, which includes for use in perforator veins – AngioDynamics' intended expansion in regards to *its* Indications for Use.

H. PERFORMANCE DATA

The performance evaluation of the proposed 400μm Perforator and Accessory Vein Ablation Kit is centered around the clinical study 'SECURE Study', which was performed in compliance with Good Clinical Practice (GCP) and in accordance to the international standard AAMI/ANSI/ISO 14155:2011 – "Clinical Investigation of Medical Devices for Human Subjects: Good Clinical Practice".
Furthermore, the proposed 400μm Perforator and Accessory Vein Ablation Kit has demonstrated successful results based upon the conclusions of the clinical testing per the above guidance and standard, including:

- Primary objective of acute primary ablation success; and,
- Secondary objectives to evaluate the post-procedural clinical outcomes.

I. CLINICAL STUDY (For Perforator Study)

The SECURE STUDY was conducted to evaluate the safety and effectiveness of the 400μm Perforator and Accessory Vein Ablation Kit when used to treat Incompetent Perforator Veins (IPVs). This was a single-arm, prospective, multi-center, non-blinded clinical trial. The study population included patients diagnosed with perforating vein insufficiency who were deemed by their treating clinician to be eligible for treatment by endovascular ablation. The primary objective of the study was to evaluate the VenaCure EVLT 400 μm Fiber Procedure Kit when used to treat Incompetent Perforator Veins (IPVs). For the primary endpoint of "acute primary ablation success," 96 of 125 treated IPVs (ITT Population) at the 10-day visit met the primary endpoint of acute primary ablation success, for a success rate of 76.8%. In the generalized estimating equation (GEE) model specified in the protocol and used to evaluate the primary endpoint, this resulted in a 76.9% model success rate, statistically significantly above the performance goal of 70% (p=0.033). The table below provides details of the SECURE STUDY.

Intent to Treat (ITT) Set				
Site	**Number of Patients**	**Number of IPVs Treated**	**Number of IPV Successes**	**Range of % Success**
100	11	11	2 – 43	28.6 – 100.0%
101	29	56		
102	9	11		
103	13	18		
104	11	15		
106	4	7		
107	6	7		

Adverse Events (Safety Population)

A total of 6 adverse events were reported during this clinical study, that were either procedure and/or device related. They include the following: deep vein thrombosis; venous thrombosis limb; thrombophlebitis superficial; skin ulcer; wound; procedural pain.

J. CONCLUSION

Based upon successful results of clinical testing, in addition to the responses to questions posed within FDA's 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent to the predicate devices.