June 18, 2019

Angiodynamics
Troy Roberts
Director, Regulatory Affairs
26 Forest Street
Marlborough, Massachusetts 01752

Re: K183385
Trade/Device Name: NanoKnife System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: OAB
Dated: May 22, 2019
Received: May 23, 2019

Dear Troy Roberts:

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,

Long Chen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183385

Device Name
NanoKnife System

Indications for Use *(Describe)*
The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.

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 – K183385

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

Submitter Information

Company:	Angiodynamics 26 Forest Street Marlborough, MA 01752 USA Telephone: 508-930-0266 Fax: 508-658-7934 troberts@angiodynamics.com
Contact:	Troy Roberts Director Regulatory Affairs Angiodynamics 26 Forest Street Marlborough, MA 01752 USA Telephone: 508-930-0266 Fax: 508-658-7934 troberts@angiodynamics.com

Date Summary Prepared:	June 18, 2019

Name of the Device

Trade Name:	NanoKnife System
Common Name:	Low energy direct current ablation device
Classification Name:	Low Energy Direct Current Thermal Ablation System
Review Panel:	General & Plastic Surgery (SU)
Regulation:	878.4400
Class:	Class II
Product Code:	OAB

Equivalence Claimed to Predicate Device

The NanoKnife System is equivalent to the NanoKnife System Version 2.2.1 (K150089), manufactured by Angiodynamics, Inc.

Device Description

The subject device is substantially equivalent to the predicate device. The NanoKnife System is a software-controlled low-energy direct-current (LEDC) generator which surgically ablates soft tissue. Included for use with the system are the NanoKnife Single Electrode Probes and optional Probe Spacer. With the NanoKnife System, a voltage applied between pairs of probes in a series of pulses. The waveform of the voltage is adjustable as determined by clinician-chosen parameters. These parameters include volts/cm, pulse length, number of pulses to be delivered between electrode pairs, the distance between probes, and the timing mode (90PPM or ECG synchronization). Up to six probes may be placed in an array within the tissue. The probes of the array are matched as pairs by the system. When probes are activated via a foot-pedal, the scheduled voltage is delivered to tissue between subsequent pairs of probes. Soft tissue between the probes is ablated.

Intended Use

The intended use of the predicate device and the subject device are identical. The intended use is for the surgical ablation of soft tissue.

Indications for Use

The NanoKnife System with six outputs is indicated for the surgical ablation of soft tissue.

Summary of Similarities and Differences in Technological Characteristics and Performance between the Predicate and Subject Device

The principle of operation of the subject device is identical to the predicate device. For the subject device, the available ablation parameters (pulse amplitude, pulse length, maximum energy per pulse, etc.) are identical to the Predicate device. Two probe configurations options that were available in the predicate device NanoKnife 2.2.1 were deleted in the subject device: bipolar probe; star shaped six probe array.

The physical design of the device has been modified, primarily to replace electronic components which have become obsolete, and to ensure conformance with the 4th edition of IEC 60601-1-2. In addition, device firmware was updated to support the new components, and the User Interface software was updated. Except for improving the EMC performance to comply with the new revision of IEC 60601-1-2, these modifications did not alter the performance of the device.

The use of RFID to read tags within the probe connectors was introduced. The RFID function assures that only compatible NanoKnife Probes which have not expired are used with the NanoKnife 3.0 system.

Biocompatibility

The patient contact materials are identical to the predicate device, however additional biocompatibility testing in accordance with ISO 10993-1:2009/(R) 2013 was performed because

of changes that have occurred in the consensus standard since the date that the original testing included in the Predicate Device submission (K150089) was performed.

Sterilization

The design of the sterilized disposable probes and probe spacer, the sterile packaging and the sterilization cycle are identical between the subject device and the predicate device, however additional testing was performed because of changes that have occurred in the relevant consensus standards (ISO 11135 2nd Edition, ISO 10993-7 2nd Edition, and ASTM F1980-07) since the date that the original testing included in the Predicate Device submission (K150089) was performed.

Safety Data

Device safety was evaluated against the following published consensus standards and FDA guidance documents.

- ES60601-1:2005/(R)2012 And A1:2012
- IEC 60601-1-2 Edition 4.0 2014-02
- IEC 60601-1-6 Edition 3.1 2013-10
- ISO 10993-1:2009/(R)2013
- ISO 10993-7:2008-10-15 Second edition

Performance Data

Device performance was evaluated against the following published consensus standards and FDA guidance documents.

- ANSI C63.27:2017
- ASTM D4169
- ASTM F1886-98
- ASTM F1980-07
- EN 301 489-1
- EN 301 489-3
- IEC 62304 Edition 1.1 2015-06
- FDA guidance document: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery, dated August 15, 2016

To address the recommendations contained in the FDA Guidance document "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery", specifically section E (System Testing), subsection 1 (Thermal Effects on Tissue), an animal study was conducted. The purpose of the testing is to characterize how the device performs over the expected range of operating conditions. The overall performance of the subject device was similar to the performance of the predicate device. There was significant variability observed in ablation volume measurements, however this variability can be attributed to specific experimental factors that are not related to the version of the

NanonKnife system under test. The P-value (0.670) for the comparison of mean ablation volume between the Predicate device NK 2.2 and the Subject device NK 3.0, supports the substantial equivalence of the two systems.

Conclusion

The subject NanoKnife System is substantially equivalent to the predicate NanoKnife System (K150089). The device modifications included in this 510(k) Premarket Notification do not affect the cleared intended use or the fundamental technological characteristics of the predicate. The subject device is as safe and effective as the predicate device.