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

June 18, 2015

Angiodynamics Incorporated
Ms. Suzanne Goodman
Senior Regulatory Affairs Manager
26 Forest Street
Marlborough, Massachusetts 01752

Re: K150089
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 18, 2015
Received: May 19, 2015

Dear Ms. Goodman:

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)*
K150089

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)*

X 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 – NanoKnife System

Date Prepared: 16 January, 2015

**A. Sponsor**

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury Avenue
Queensbury, NY 12804

**B. Contact**

Suzanne Goodman
Senior Regulatory Affairs Manager
AngioDynamics, Inc.
26 Forest Street
Marlborough, MA 01752
508-658-7942

**C. Device Name**

| | |
|---|---|
| Trade Name: | NanoKnife System |
| Common/Usual Name: | Low energy direct current ablation device |
| Classification Name: | 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories |
| Product Code: : | OAB |

**D. Predicate Device(s)**

| | |
|---|---|
| Trade Name: | NanoKnife System (K102329) |
| Common/Usual Name: | Low energy direct current ablation device |
| Classification Name: | 21 CFR 878.4400, Electrosurgical Cutting and Coagulation Device and Accessories |
| Classification Panel: | General and Plastic Surgery |

**E. Device Description**

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, electrical current is delivered between pairs of probes in a series of pulses. The waveform of the current is adjustable as determined by clinician-chosen parameters. These parameters include volts/cm, pulse length, number of pulses to be delivered between electrode pairs, distance between probes, and the timing mode (90PPM, 240PPM 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 current is delivered to tissue between subsequent pairs of probes. Soft tissue between the probes is ablated.

**F. Intended Use and Indications for Use**

The intended use of the NanoKnife System is identical to the intended use of the predicate device, the NanoKnife System subject of K102329:

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

The NanoKnife System is used in the same manner as the predicate device, the NanoKnife System subject of K102329.

**G. Summary of Similarities and Differences in Technological Characteristics and Performance between the Predicate and Modified Device**

The NanoKnife Generator, subject of this 510(k) Premarket Notification, is a modification to the NanoKnife Generator submitted in K102329. The available ablation parameters, pulse amplitude, pulse length, maximum energy per pulse, and energy storage between recharges of the NanoKnife Generator are all identical to the predicate device. The design modifications to the NanoKnife Generator consist of hardware, firmware, software and labeling changes. **Table 1** below provides a summary of these changes.

**Table 1. Summary of Design Modifications**

| **Hardware and Specifications** |
|---|
| Component changes due to availability of components and to improve the electromagnetic (EMC)/electromagnetic (EMI) profile of the device to comply with IEC 60601-1 3rd ed. standards. |
| Increased shelf life specification of Single Electrode Probes to 3 years (no design modification or change to functionality) |
| **Firmware** |
| Programming and code changes to:<br>• eliminate system shutdowns upon detection of over-current conditions<br>• debug programming (continuous device life-cycle improvement)<br>• enhance software diagnostics |
| **Software** |
| Programming and code changes to:<br>• remove non-English Languages<br>• disable radio frequency identification (RFID) functionality<br>• enable functions in administrator mode (not available to users)<br>• add clearer warning messages to the user when using 240 PPM and 90 PPM pulse modes<br>• debug programming (continuous device life-cycle improvement) |
| **Labeling** |
| System Manual Updates - reorganized and revised safety section, including expanded discussion of High Current and Over-Current conditions |
| User Manual - Removed discussion of RFID functions |
| User Manual - Add information per IEC 60601-1 3rd ed. |
| Pouch/Box Label – Administrative changes |

The NanoKnife Single Electrode Probes and optional Probe Spacer are identical to the NanoKnife Single Electrode Probes and Probe Spacer utilized by the predicate NanoKnife System. Two Single Electrode Probes (15cm and 25cm lengths) are offered with the modified device. The manual actuation, material, tip configuration, and sterilization method of the NanoKnife Single Electrode Probes are all identical to the predicate device.

Furthermore, there have been no changes made to the way ablation procedures will be performed using the NanoKnife System as compared to the predicate device. Users trained in the use of the NanoKnife System predicate device are instructed to confirm that the ablation was successful using standard imaging techniques. Like its predicate device, the NanoKnife System is a tool for surgically ablating soft tissue. Both the predicate device and the NanoKnife System require visual confirmation of ablation using standard imaging techniques (e.g., CT or ultrasound) following the procedure.

**H. Performance Data**

The modified NanoKnife System Generator was tested per the following to support a determination of substantial equivalence:

- Performance testing, including:
  - ECG synchronization operation
  - Power supply regulation
  - AC/DC board voltages
  - Charge bank verification
  - Hardware safety measures (i.e., over/under current pulse intervention, overlength pulse, Field Programmable Gate Array firmware functionality, etc.)
  - Voltage and current accuracy
  - Pulse duration
  - Minimum capacitance
  - Pulse amplitude
  - Pulse frequency
  - Pulse intervals
  - Pulse count
  - Maximum energy delivered
  - Emergency Stop Button functionality
- Ship testing - environmental and vibration/handling
- Reliability testing
- EMC testing (EN 60601-1-2:2001/A1:2006)
- Electrical safety testing (IEC 60601-1-2:2001/A1:2004)
- Software validation testing

The test results verify that the NanoKnife System meets all the specified performance specifications and thus, is substantially equivalent to the predicate device.

Additionally, AngioDynamics performed a series of ablation and thermal zone calculations with physical parameters input to the Pennes bioheat model utilizing an industry standard differential equation and finite element analysis tool for physics and biological systems. The results of worst-case modeling indicate that potential thermal ablation volumes lie within the boundaries of electroporation volumes where clinically-relevant input parameters are utilized.

**I. Conclusion**

The modified NanoKnife System is substantially equivalent to the predicate NanoKnife System (K102329). The design modifications included in this 510(k) Premarket Notification do not affect the cleared intended use or indications for use. Nor do the design modifications alter the fundamental

technological characteristics of the predicate or raise new questions of safety and effectiveness. Where changes in technology occur, the results of performance testing confirm the modified NanoKnife System is substantially equivalent to the predicate device.