December 6, 2024

Angiodynamics, Inc.
Brandon Brackett
Senior Manager, Global Regulatory Affairs
26 Forest Street
Suite 100
Marlborough, Massachusetts 01752

Re: K242687
Trade/Device Name: NanoKnife Generator (H78720300301US0);
NanoKnife Single Electrode Activation Probe, 15 cm (H787204001090);
NanoKnife Single Electrode Activation Probe, 25 cm (H787204001100); NanoKnife Single Electrode Probe Spacer (H787204003010)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and accessories
Regulatory Class: II
Product Code: OAB
Dated: September 6, 2024
Received: November 4, 2024

Dear Brandon Brackett:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K242687

Device Name

NanoKnife Generator (H78720300301US0);
NanoKnife Single Electrode Activation Probe, 15 cm (H787204001090);
NanoKnife Single Electrode Activation Probe, 25 cm (H787204001100);
NanoKnife Single Electrode Probe Spacer (H787204003010)

Indications for Use *(Describe)*

The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k) #: K242687

# 510(k) Summary

Prepared on: 2024-11-04

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Angiodynamics, Inc. |
| Applicant Address | 26 Forest Street Suite 100 Marlborough MA 01752 United States |
| Applicant Contact Telephone | 9788217678 |
| Applicant Contact | Mr. Brandon Brackett |
| Applicant Contact Email | bbrackett@angiodynamics.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | NanoKnife Generator (H787203003O1US0);<br>NanoKnife Single Electrode Activation Probe, 15 cm (H787204001090);<br>NanoKnife Single Electrode Activation Probe, 25 cm (H787204001100);<br>NanoKnife Single Electrode Probe Spacer (H787204003010) |
| Common Name | Low Energy Direct Current Thermal Ablation Device |
| Classification Name | Low Energy Direct Current Thermal Ablation System |
| Regulation Number | 878.4400 |
| Product Code(s) | OAB, N/A |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K183385 | NanoKnife System | OAB |

## Device Description Summary

21 CFR 807.92(a)(4)

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. The predicate device has not been the subject of a design-related recall.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

This 510(k) does propose a modification to the Indications for Use; specifically, to add "…including prostate tissue" to the existing statement. This does not constitute a new intended use, as the Indications for Use are simply becoming more specific in terms of the "soft tissue" intended to be treated. This level of specificity is supported by the human clinical trial data (PRESERVE) included as part of this submission.

## Technological Comparison

21 CFR 807.92(a)(6)

The proposed NanoKnife System has the identical technological characteristics as the predicate, and is unchanged as compared to the currently cleared version of the system. A comparison has been included in a tabular format, within the appropriate attachment, to demonstrate the unchanged nature of the proposed device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Angiodynamics conducted Hardware Verification Testing, Functional Testing, Generator Reliability Testing, and Generator Packaging/ Labeling Testing, and provided them in the predicate K183885 submission. None of this testing was required to be repeated in support of this proposed Indications for Use modification, and as a result refers the FDA to the predicate K183885 for the full reports.

The NanoKnife System is a device used for tissue ablation using irreversible electroporation (IRE), a method of focal ablation which uses high voltage electrical pulses to change the permeability of the cell membrane leading to cell death. During the procedure, electrical pulses between probe pairs produce an electric field which induces electroporation of cells within the targeted ablation area. The NanoKnife System with six outputs is currently indicated for the surgical ablation of soft tissue by the United States Food and Drug Administration (FDA). The study, Pivotal Study of the NanoKnife System for Ablation of Prostate Tissue in an Intermediate-Risk Patient Population (PRESERVE), was a prospective, nonrandomized pivotal study to evaluate the safety and effectiveness of the NanoKnife System to ablate prostate tissue in subjects with intermediate-risk prostate cancer (NCT04972097). The primary effectiveness endpoint, the rate of subjects with a negative in-field biopsy at 12 months, was compared to a predefined performance goal of 0.52. The performance goal was based on the Sonablate 450 de novo summary (DEN150011), which reported a negative biopsy rate of 61% at 12 months (missing data imputed as positive), minus a 9% non-inferiority margin. The primary safety endpoint of the PRESERVE study was the incidence of adverse events (AEs) by type and Common Terminology Criteria for Adverse Events (CTCAE) v5.0 severity through 12 months; with a minimum of 100 subjects, the study was able to detect at least one significant AE of any type with over 80% accuracy if the true event rate was at least 1.6%.

A total of 121 subjects were enrolled and subsequently treated with the NanoKnife System between March 2022 and July 2023 across 17 clinical sites. Data were collected at screening, baseline, NanoKnife treatment, 3-10 days post-procedure, and 1, 3, 6, 9, and 12 months post-procedure. Subjects were assessed for AEs throughout study participation.

This study was performed in compliance with ISO14155:2020 – Clinical Investigation of Medical Devices for Human Subjects and Good Clinical Practice for the protection of human subjects, including the archiving of essential documents.

The primary effectiveness endpoint, the rate of subjects with a negative in-field biopsy at 12 months, was compared to a predefined performance goal of 0.52. In the primary analysis where missing biopsy information at 12 months was imputed as positive, 71.1% of subjects (86/121; 95% confidence interval: 62.1%, 79.0%) had a negative in-field biopsy at 12 months, meeting the predefined performance goal of 52%. In a supplementary analysis removing the 14 subjects without biopsy information, 80.4% of subjects (86/107; 95% confidence interval: 71.6%, 87.4%) had a negative in-field biopsy at 12 months. In the analysis of the primary safety endpoint, 86.0% of subjects (104/121; 95% confidence interval: 78.5%, 91.6%) experienced an AE. One death was reported (on study day 335) that was not related to NanoKnife; all other AEs were Grade 3 or less. Only three AEs related to the NanoKnife System procedure were CTCAE grade 3 and there were no Grade 4 or 5 events related to the NanoKnife System procedure. The present study confirmed that the safety and performance of the NanoKnife System for the ablation of prostate tissue were established in subjects with intermediate-risk prostate cancer. The device can be a minimally invasive treatment approach for this patient population.