March 24, 2026

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

Re: K253198
Trade/Device Name: NanoKnife Generator (H78720300351US0)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and accessories
Regulatory Class: II
Product Code: OAB
Dated: February 13, 2026
Received: February 13, 2026

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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 R. Kreitz -S

for 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253198

Please provide the device trade name(s).

NanoKnife Generator (H78720300351US0)

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253198

510(k) Summary

Prepared on: 2026-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Angiodynamics
Applicant Address	26 Forest Street Suite 100 Marlborough MA 01752 United States
Applicant Contact Telephone	978-493-7393
Applicant Contact	Mr. Brandon Brackett
Applicant Contact Email	bbrackett@angiodynamics.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	NanoKnife Generator (H78720300351US0)
Common Name	NanoKnife System
Classification Name	Low Energy Direct Current Thermal Ablation System
Regulation Number	878.4400
Product Code(s)	OAB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K242687	NanoKnife System	OAB

Device Description Summary

21 CFR 807.92(a)(4)

The subject device is substantially equivalent to the predicate device. The NanoKnife Generator is part of the NanoKnife System, and is a software-controlled low-energy direct-current (LEDC) generator which surgically ablates soft tissue, including prostate tissue. Included for use within the NanoKnife 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 (including prostate tissue) between the probes is ablated.

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)

The Indications for Use for the predicate NanoKnife Generator and the proposed NanoKnife Generator are the same, and are not impacted by this proposed 510(k).

Technological Comparison

21 CFR 807.92(a)(6)

The proposed NanoKnife Generator differs slightly as compared to the predicate NanoKnife Generator, as the proposed NanoKnife

Generator has been updated with newly-selected components. While the components between the two may differ, the proposed and predicate devices remain substantially equivalence to one another per the definition within FDA Guidance. Specifically, the modifications do not impact the overall design of the product, principle of operation, energy source(s), mechanism of action, or any parameters associated with the use of the NanoKnife Generator. Functionality, safety, and performance have been demonstrated to not be impacted by means of a robust regiment of applicable testing, including but not limited to EMC testing, software testing, and design verification testing.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

In support of the proposed NanoKnife 3.5 Generator, Angiodynamics conducted a robust series of non-clinical testing demonstrating the safety and efficacy of the device. This testing included:

1) Basic Safety and Essential Performance (Electrical Safety) Testing (IEC 60601-1; IEC 60601-1-2)
2) EMC and Software Testing (IEC 60601-1; IEC 60601-1-2; IEC 62304; ANSI C63.27; IEC TS 60601-4-2, FDA Guidance for Industry and Food and Drug Administration Staff, "Electromagnetic Compatibility (EMC) of Medical Devices)
3) GUI Software Validation Testing (IEC 62304)
4) GUI Software Regression Testing (IEC 62304)
5) Generator System Functional Testing
6) Hardware Design Verification Testing
7) Generator Reliability Design Verification Testing
8) Generator Packaging and Labeling Design Verification Testing (ASTM D4169-22; ISO 15223-1)

All testing demonstrated acceptable results and supports the conclusion that the proposed NanoKnife 3.5 Generator is safe and effective for its intended use.

Not applicable - no Clinical Tests submitted.

AngioDynamics, Inc. has also assessed the proposed NanoKnife 3.5 Generator from a cybersecurity perspective. Specifically, the proposed NanoKnife 3.5 Generator shares the same fundamental cybersecurity features as the predicate NanoKnife 3.0 Generator. The primary cybersecurity design objective was to minimize the system's attack surface. AngioDynamics, Inc. developed a Threat Assessment and implemented its findings in order to achieve this goal. Lastly, AngioDynamics, Inc. complies with "Guidance for Industry and Food and Drug Administration Staff - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (June 2025)

Per the Substantial Equivalence discussion pertaining to the proposed NanoKnife 3.5 Generator, Angiodynamics has demonstrated via the testing it has conducted on the subject device that it is equivalently safe, effective, and performs as well as the predicate NanoKnife 3.0 Generator. The testing regiment of the proposed NanoKnife 3.5 Generator was design to ensure a side-by-side comparison of tests and results was possible, in order to arrive at the conclusions described above.