March 21, 2024

Aerin Medical Inc.
Teri Feeley
Regulatory Affairs Manager
2565 Leghorn St.
Mountain View, California 94043

Re: K240253
Trade/Device Name: Reach Needle
Regulation Number: 21 CFR 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: Class II
Product Code: BSP
Dated: January 26, 2024
Received: January 30, 2024

Dear Teri Feeley:

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.

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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*

K240253

Device Name

Reach Needle

Indications for Use *(Describe)*

The Reach Needle is used for in injecting local anesthetics into a patient to provide regional anesthesia.

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) Summary

General Information

Submitter Information	
Company:	Aerin Medical Inc.
Submitter address:	2565 Leghorn St. Mountain View, CA 94043
Contact Person:	Teri Feeley Regulatory Affairs Manger Phone: 210-827-1618
Establishment Registration Number:	3011625895
Date Prepared:	15 Mar 2024
Name of Device	
Brand Name:	Reach Needle
Common Name:	Needle, Conduction, Anesthetic (w/wo introducer)
Classification Name:	Anesthesia conduction needle
Device Class:	Class II
Product Code:	BSP
CFR Regulation:	21 CFR 868.5150
Predicate Device:	Entellus Reinforced Anesthesia Needle (K163435)
Device Description	
The Reach Needle is a sterile, single use, 4-inch-long needle used for administering anesthetic solutions for regional anesthesia. The Reach Needle is 27-gauge needle that is reinforced to reduce needle flex during administration of anesthesia solutions. The needle tip is a short bevel quincke style tip that extends approximately 2mm past the reinforcing shaft, providing a distal stop for consistent injection depth. The distal end of the needle has a slight bend to help access difficult to reach areas such as nasal anatomy. The needle hub is compatible with luer lock connectors. The Reach Needle is intended for use in adults (≥ 22 years).	
Indications for Use	
The Reach Needle is used for injecting local anesthetics into a patient to provide regional anesthesia.	
Summary of Technological characteristics compared to the predicate device	
The subject device has the same technological characteristics as the predicate including the principle of operation, performance, and design features. The subject device and predicate device both have a stainless-steel cannula that is reinforced with a plastic hub to deliver local anesthetic solutions for regional anesthesia. Both devices are 27-gauge needles with a reinforced sleeve, a quincke style tip, 2mm distal stop, and a bend incorporated at the distal end of the reinforced cannula. The subject device cannula is 4 inches long with a 30° bend and a Short Bevel tip; whereas the predicate device cannula is 3.5 inches long with an 18° bend and long, beveled tip.	

510(k) Summary

	Subject Device	Predicate Device
Intended Use	Same	For use in injecting local anesthetics into a patient to provide regional anesthesia.
Use	Same	Single use
Materials	Same	Stainless steel needle and plastic hub
Hub design	Same	Standard luer lock connector
Needle gauge	Same	27G
Needle length	4 inches	3.5 inches
Device reinforcement	Same	Reinforced sleeve
Needle bend	30 degree bend	18 degree bend
Insertion stop (distal stop)	Same	2mm insertion depth stop
Needle tip	Same	Quincke style
	Short bevel	Long bevel

Summary of non-clinical test

Device Performance was tested to comply to:

- ISO 80369-7
- ISO 9626
- ISO 7864

Package Integrity per ISO 11607-1 and 11607-2.

Reach needle is an externally communicating device with direct tissue contact for limited duration; biocompatibility testing is in compliance with ISO 10993-1 and included:

- Cytotoxicity
- Irritation
- Sensitivity
- Systemic toxicity
- Pyrogenicity

Summary of clinical test

Clinical testing was not necessary for this device.

Conclusion

The subject device is substantially equivalent to the predicate device based on a comparison of the intended use, indications for use, and technological characteristics and the minor differences do not raise new questions of safety or effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.