April 17, 2026

Navi Medical Technologies
Zorana Mayooran
QA/RA Specialist
Level 2, 700 Swanston St.
Carlton, VIC 3053
Australia

Re: K260929
Trade/Device Name: Neonav ECG Tip Location System
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: March 20, 2026
Received: March 20, 2026

Dear Zorana Mayooran:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

MARCO CANNELLA -S

for:

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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.	K260929

Please provide the device trade name(s).

Neonav ECG Tip Location System

Please provide your Indications for Use below.

Neonav is indicated for navigation and positioning of central venous access devices (CVADs) of at least 1Fr in size. Neonav provides real-time catheter tip location information by using the patient's cardiac electrical activity. Neonav is indicated for use as an alternative method to chest X-ray and fluoroscopy for all central venous access device tip placement confirmation.
In adult patients and in adolescents (greater than 12 through 21 years of age), Neonav can be used with CVADs such as peripherally inserted central catheters (PICCs), centrally inserted central catheters (CICCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), Neonav can be used with PICCs and with CICCs; in infants (greater than 1 month to 2 years of age), Neonav can be used with PICCs and CICCs; and in neonates (from birth to 1 month of age), Neonav can be used with PICCs, CICCs, and umbilical venous catheters (UVCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.
Limiting but not contraindicated situations for use of the Neonav are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to central venous access device insertion, the use of an additional method is required to confirm catheter tip location.

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

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

510(k) #: K260929

510(k) Summary

Prepared on: 2026-03-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Navi Medical Technologies
Applicant Address	Level 2, 700 Swanston Street Carlton VIC 3053 Australia
Applicant Contact Telephone	+6139059 4919
Applicant Contact	Dr. Zorana Mayooran
Applicant Contact Email	zorana@navitechnologies.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Neonav ECG Tip Location System
Common Name	Percutaneous, implanted, long-term intravascular catheter
Classification Name	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Number	880.5970
Product Code(s)	LJS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241910	Neonav ECG Tip Location System	LJS

Device Description Summary

21 CFR 807.92(a)(4)

The Neonav ECG Tip Location System (Neonav) is a non-invasive medical device that analyzes electrocardiographic signals (ECG) to track the location of central venous access devices (CVADs) in patients' blood vessels during placement and post placement in real time via a display.

Catheter position in the vasculature is analyzed based on the patient's intravascular ECG (I-ECG). An I-ECG is recorded via the catheter tip from within the blood vessels of a patient. For the conductive fluid method, the sterile Neonav ECG Adapter and Adapter Cable are used whereas for guidewire/stylet method, the sterile Neonav ECG clip cable is used. These components allow the electrical impulses detected at the catheter tip to be recorded by a non-sterile Acquisition Unit and analyzed by the Neonav Console to assist in determining the catheter tip position. The Neonav Console can be controlled via a touch screen interface or a Remote enclosed in a sterile cover. The Neonav Console displays real-time surface ECG and I-ECG signals, highlighted QRS complex, max measured P-wave, the patient's heart rate, and other device performance indicators. A surface electrode is placed on the subject to act as a reference electrode. A second surface electrode is placed on the subject for noise reduction.

Neonav components are designed to attach easily to standard catheter and IV therapy components via standard luer lock connections. The only patient contacting component of the Neonav is the ECG Adapter. It has indirect contact with the patient via fluids and is composed of biocompatible polycarbonate and stainless steel.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Neonav is indicated for navigation and positioning of central venous access devices (CVADs) of at least 1Fr in size. Neonav provides real-time catheter tip location information by using the patient's cardiac electrical activity. Neonav is indicated for use as an alternative method to chest X-ray and fluoroscopy for all central venous access device tip placement confirmation.

In adult patients and in adolescents (greater than 12 through 21 years of age), Neonav can be used with CVADs such as peripherally inserted central catheters (PICCs), centrally inserted central

catheters (CICCs), implantable ports, and hemodialysis catheters; in children (greater than 2 to 12 years of age), Neonav can be used with PICCs and with CICCs; in infants (greater than 1 month to 2 years of age), Neonav can be used with PICCs and CICCs; and in neonates (from birth to 1 month of age), Neonav can be used with PICCs, CICCs, and umbilical venous catheters (UVCs). In each specific age group, the CVAD type and size must be chosen and the CVAD must be used according to the CVAD's indications and instructions for use.
Limiting but not contraindicated situations for use of the Neonav are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to central venous access device insertion, the use of an additional method is required to confirm catheter tip location.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Neonav has equivalent indications for use with the predicate with the following adjustment:
a) addition of umbilical venous catheters (UVCs) to the list of lines Neonav can be used with in neonates (from birth to 1 month of age).
The intended use of the subject device is equivalent to that of the predicate: "The intended use of Neonav is to support navigation and tip positioning of central venous access devices. Neonav can be used as an alternative method to fluoroscopy and chest X-ray for central venous access device tip placement confirmation". Umbilical venous catheters are a type of central venous access device used in the neonatal intensive care unit. Once inserted, UVCs terminate at a target location in the inferior vena cava (IVC) – this target location is already part of the predicate device K241910. Technological, software, and usability characteristics of the subject device and predicate device are equivalent. Therefore, the addition of UVCs to the neonatal group does not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Neonav subject device has the same technological characteristics as the predicate device, which include device design, device connectivity and/or interfaces, materials, principles of operation, energy source, and software capabilities. The only difference is that the subject device offers the user an option to select the UVC line on screen during the procedure set-up (via the software graphical user interface, GUI). Thereafter, the subject device continues to be used in the same way as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Retrospective sub analysis conducted on PICC and UVC design validation datasets obtained from observational clinical studies showed a success rate of > 90% for all the software parameters assessed.