January 19, 2025

Navi Medical Technologies
Zorana Mayooran
QA/RA Specialist
700 Swanston Street
Melbourne, VIC 3053
Australia

Re: K241910
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: June 30, 2024
Received: July 1, 2024

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 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,

Aneesh S. Deoras -S

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

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.

510(k) Number *(if known)*
K241910

Device Name
Neonav ECG Tip Location System

Indications for Use *(Describe)*
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) and in neonates (from birth to 1 month of age), Neonav can be used with PICCs and CICCs. 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.

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.

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510(k) #: K241910

510(k) Summary

Prepared on: 2024-12-20

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Navi Medical Technologies
Applicant Address	700 Swanston Street Melbourne VIC 3053 Australia
Applicant Contact Telephone	+61481882530
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
K141634	Nautilus Delta	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) and in neonates (from birth to 1 month of age), Neonav can be used with PICCs and CICCs. 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 to the predicate with the following adjustments:
a) Neonav is indicated to be used with PICCs in infants and neonates (in addition to CICCs for this patient population).
b) Neonav allows for use of catheter sizes of 1Fr and above, instead of 3Fr and above.
These changes are supported by the most current literature analysis confirming safety and effectiveness of PICCs in infants and neonates and non-clinical bench tests demonstrating that Neonav is able to capture data from lines down to 1Fr. They are still within the scope of the current intended use which states "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". The intended use of the Neonav is equivalent to the intended use of the predicate device.
c) To align with recent standards and guidance documents the terminology CVAD has been adopted in place of the generic term of CVC to refer to the family of vascular access devices terminating in a central location (INS Infusion Therapy Standard of Practice 9th Ed. ISSN 1533-1458, INS Policies and Procedure for Infusion Therapy: Neonate to Adolescent 3rd Ed). CICC has been adopted to refer to specific devices that are inserted in the jugular or subclavian vein and terminate in the SVC (Vascular Access in Neonates and Children ISBN 978-3-030-94708-8).

Technological Comparison

21 CFR 807.92(a)(6)

The Neonav has features, materials and technological characteristics equivalent to the predicate device. Notable differences that do not raise new questions about safety and effectiveness are:
a) Neonav does not have a printer. It allows patient summary reports to be copied to a USB rather than sent directly to a printer.
b) Neonav's remote and acquisition unit are separate items, rather than a single item
c) Neonav Acquisition Unit is wired (USB cable) rather than wireless (Bluetooth)
d) Neonav medical application is standalone, instead of mobile.
e) Neonav does not provide computation of ECG signal for navigation. Neonav displays the intravascular ECG to the user, and the user makes their own decision regarding catheter navigation based on the presentation of the real-time intravascular ECG signal.
f) Neonav highlights the complete QRS complex instead of placing red marks on the R-wave.
g) Neonav can display multiple frozen I-ECG waveforms simultaneously with insertion depth readings and spot check readings to aid in finding the depth with the max measured P-wave.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Testing was conducted to verify and validate performance requirements and determine substantial equivalence. The following guidance documents or FDA recognized consensus standards were used/referenced for testing:
• ISO 10993-1: Fifth edition 2018-08 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
• 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]
• ISO 11135-7 Sterilization of health-care products —Ethylene oxide —Requirements for the development, validation and routine control of a sterilization process for medical devices
• ISO 11135-2 Sterilization of health care products —Ethylene oxide —Part 2: Guidance on the application of ISO 11135-1
• ISO 11607-1 Second edition 2019-02 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (including all applicable ASTM standards to verify the characteristics of the packaging material)
• ISO 11607-2: Second edition 2019-02 Packaging for terminally sterilized medical devices — part 2: validation requirements for forming, sealing and assembly processes
• 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.
• ISO 14971: 2019 Medical devices - Applications of risk management to medical devices.
• EN ISO 13485 Medical devices. QMS. Requirements for Regulatory Purposes.
• ANSI AAMI IEC 60601-1: ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

• IEC 60601-1-2: Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
• IEC/TR 60601-4-2, IEC /TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
• IEC 60601-1-6: 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
• IEC 62366-1: 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Application of usability engineering to medical devices
• IEC 62304: 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
• IEC 62133-2: 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
• IEC 60601-2-27: 60601-2-27 Edition 3.0 2011-03 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
• ISO 20417: First edition 2021-04 Corrected version 2021-12 Information supplied by the manufacturer of medical devices
• IEC 60529 Degree of Protection Provided By Enclosures (IP Code)
• ISO 80369-7:2016 80369-7 Second edition 2021-05 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
• ANSI/AAMI EC53:2013 (R2020) ECG Trunk Cables And Patient Leadwires
• ASTM D543 Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents
• ASTM F88/F88M-21 Standard Test Method for Seal Strength of Flexible Barrier Materials
• ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
• ASTM D7386-16 Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems
• ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
• ISTA 3A 2018 General Simulation Performance Test - Parcel Delivery System Shipments 70 kg (150lb) or Less
• ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
• AAMI TIR57 AAMI TIR57:2016, Principles for medical device security - Risk management
• Off-The-Shelf Software Use in Medical Devices –Guidance for Industry and Food and Drug Administration Staff (August 11, 2023)
• Content of Premarket Submissions for Device Software Functions – Guidance for Industry and FDA Staff, June 14, 2023
• Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff, September 27, 2023
• Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, September 2023
• Applying Human Factors and Usability Engineering to Medical Devices, Guidance for Industry and Food and Drug Administration Staff, February 2016

The subject device, the Neonav ECG Tip Location System, met all predetermined acceptance criteria as required from the listed standards and has demonstrated substantial equivalence to the predicate device.

Based on intended use, technological characteristics, and performance testing it is concluded that the subject device, the Neonav ECG Tip Location System, is substantially equivalent to the predicate device.