November 17, 2025

Piccolo Medical, Inc.
% Alexia Haralambous
Director, Regulatory Affairs
2790 Mosside Blvd, #800
Monroeville, Pennsylvania 15146

Re: K252792
Trade/Device Name: PM2™ System with ECGuide™ Connector
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS, DRX, DSA
Dated: October 2, 2025
Received: October 20, 2025

Dear Alexia Haralambous:

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
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Division of Cardiac Electrophysiology,
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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)*
K252792

Device Name
PM2™ System with ECGuide™ Connector

Indications for Use *(Describe)*
The PM2™ System with ECGuide™ Connector is indicated for the positioning of central venous access devices (CVADs) of at least 1Fr in size. It provides catheter tip location information by using the patient's cardiac electrical activity. The PM2™ System with ECGuide™ Connector is indicated for use as an alternative method to chest x-ray or fluoroscopy for confirmation of all central venous access devices.

In adult patients and in adolescents (greater than 12 through 21 years of age), The ECGuide™ 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), ECGuide™ 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), ECGuide™ 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.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including
-Atrial fibrillation
-Atrial flutter
-Severe tachycardia
-Pacemaker-driven rhythm
-Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary 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.

510(k) SUMMARY

DATE PREPARED
November 12, 2025

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION
Proprietary Name/Trade Name: PM2™ System with ECGuide™ Connector
Common Name: Percutaneous, implanted, long-term intravascular catheter
Regulation Number: 21 CFR 880.5970
Class: II
Product Code: LJS, DRX, DSA
Review Panel: General Hospital

PREDICATE DEVICE IDENTIFICATION
The PM2™ System with ECGuide™ Connector is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K241910	Neonav ECG Tip Location System	✓
K240486	PM2™ System with ECGuide™ Connector	
K180560	Sherlock 3CG+™ Tip Confirmation System (TCS)	

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION
The purpose of this Special 510(k) is for the expansion of indications for use of the previously cleared PM2™ System with ECGuide™ Connector (K240486) from use in adults to pediatric populations. There have been no major changes to the device since initial clearance under K240486. The PM2™ System with ECGuide™ Connector is a device used by clinicians for bedside tip location confirmation of central venous catheters. The PM2™ System with

ECGuide™ Connector provide real-time catheter tip location information by using intravascular ECG (ivECG). The ECGuide™ Connector is connected to the distal lumen hub of a CVC and primed with saline to create an ivECG electrode at the distal tip of the catheter and allow for ECG catheter tip confirmation. The ECGuide™ Connector is used only during CVC installation, and removed once the CVC tip position is confirmed to be at the target location. The ECGuide™ Connector is electrically connected to the PM2 system which processes, displays, and stores the ECG waveforms.

INDICATIONS FOR USE

The PM2™ System with ECGuide™ Connector is indicated for the positioning of central venous access devices (CVADs) of at least 1Fr in size. It provides catheter tip location information by using the patient's cardiac electrical activity. The PM2™ System with ECGuide™ Connector is indicated for use as an alternative method to chest x-ray or fluoroscopy for confirmation of all central venous access devices.

In adult patients and in adolescents (greater than 12 through 21 years of age), The ECGuide™ 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), ECGuide™ 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), ECGuide™ 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.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-wave; including
-Atrial fibrillation
-Atrial flutter
-Severe tachycardia
-Pacemaker-driven rhythm
-Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to central catheter insertion. In these specific cases, use of an additional confirmation method is necessary to confirm catheter tip location.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device and the predicate Neonav device have the same technological characteristics for providing intravascular ECG to the end user to facilitate catheter tip confirmation. Both devices utilize a luer-lock style connector to connect to a CVC and a saline column within the lumen of the CVC to conduct the intravascular ECG signal to the tip. Furthermore, the subject device is identical to the predicate PM2™ System with ECGuide™ Connector (K240486). The technological differences between the PM2™ System and ECGuide™ Connector and the Neonav device do not raise different questions of safety and effectiveness. Both devices use

ECG for catheter tip location information. The safety of these approaches have been well established and determined to be acceptable in multiple FDA cleared devices with the same intended uses.

SUMMARY OF NON-CLINICAL TESTING

Various non-clinical tests were previously completed on the PM2™ System with ECGuide™ Connector under the K240486 submission. This testing included, but was not limited to: electrical safety, EMC, software verification and validation, cybersecurity testing, tensile strength, insertion force, corrosion resistance, catheter compatibility, leak testing, electrical hardware verification, sterile barrier packaging testing, biocompatbility, design validation, and human factors validation. This testing was not repeated in this submission as the device design has not changed.

However, additional bench testing was performed to demonstrate that Neonav is able to capture data from lines down to 1Fr. Test methods similar to that of the predicate Neonav device were used to assess this. Furthermore, a clinical literature analysis was done to support the safety and effectiveness of PICCs in adolescents, children, infants, and neonates. No clinical testing was provided to support substantial equivalence.

All tests were performed objectively following Piccolo Medical's Quality Management System using pre-approved test protocols and post-test approval of applicable test reports. Where appropriate, Piccolo Medical employed the use of FDA consensus standards and FDA guidance during each test therefore the test methods were concluded to be acceptable.

The subject PM2™ System with ECGuide™ Connector has the same intended use and fundamental technology as its legally marketed predicate devices. The performance summary and analyses included in this premarket notification support a determination of substantial equivalence.

CONCLUSION

The PM2™ System with ECGuide™ Connector is considered substantially equivalent to the predicate devices based on the testing performed, the identical indications for use, and similar technological characteristics.