September 8, 2024

Piccolo Medical, Inc.
Augustus Shanahan
CEO
218 Mississippi St
San Francisco, California 94107

Re: K240486
Trade/Device Name: PM2 System and 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: August 9, 2024
Received: August 9, 2024

Dear Augustus Shanahan:

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,

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

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)*

K240486

Device Name

PM2 System and ECGuide Connector

Indications for Use *(Describe)*

The Piccolo Medical PM2™ System with ECGuide™ Connector is indicated for the positioning of central venous catheters including PICCs. 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 central venous catheter tip placement in adult patients.

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K240486

510(k) Summary

Prepared on: 2024-08-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Piccolo Medical, Inc.
Applicant Address	218 Mississippi St San Francisco CA 94107 United States
Applicant Contact Telephone	6178424168
Applicant Contact	Mr. Augustus Shanahan
Applicant Contact Email	ashanahan@piccolomedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	PM2 System and ECGuide Connector
Common Name	Tip Location System
Classification Name	Percutaneous, implanted, long-term intravascular catheter
Regulation Number	21 CFR 880.5870
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
K160925	VPS Rhythm Device with TipTracker Technology	LJS
K200037	SmartPICC System	LJS

Device Description Summary

21 CFR 807.92(a)(4)

The PM2™ System and ECGuide™ Connector is a device used by clinicians for bedside tip location confirmation of central venous catheters. The PM2™ System and 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.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Piccolo Medical PM2™ System with ECGuide™ Connector is indicated for the positioning of central venous catheters including PICCs. 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 central venous catheter tip placement in adult patients.

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the predicate device and the subject device are the same with the exception that the predicate device indications includes the use of an optional accessory which is not relevant to the subject device (optional TipTracker Technology). The intended use of the predicate and subject device is the same.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate devices 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.

The VPS Rhythm device (K103255) also includes an optional Tip Tracker Accessory and disposable stylet for PICC navigation which is not relevant to the subject device.

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

The determination of substantial equivalence was based on an assessment of non-clinical performance data. Performance testing performed on the PM2 System and ECGuide Connector verified all device performance requirements including electrical safety, EMC, software verification and validation, tensile strength, insertion force, corrosion resistance, catheter compatibility, leak testing, electrical hardware verification, sterile barrier packaging testing, biocompatbility, design validation and human factors validation. All tests were successfully completed. The passing results supported the determination of substantial equivalence with the predicate device.

No human clinical data was provided to support substantial equivalence.

The information included in this premarket notification supports the substantial equivalence of the subject PM2 System and ECGuide Connector to the stated predicate device. The listed reference device also provides substantial equivalence support for the electrical hardware utilized in the PM2 System. The subject device has the same intended use, similar indications for use and incorporates the same fundamental technology as the legally marketed predicate device and the reference devices to which it was compared. The results of the testing included in this premarket notification support a determination of substantial equivalence.