



May 29, 2025

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

Re: K243484

Trade/Device Name: PM2+ System and SmartPICC Stylet
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS, DRX, DSA
Dated: April 30, 2025
Received: April 30, 2025

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,


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

Indications for Use

Submission Number (if known)

K243484

Device Name

PM2+ System and SmartPICC Stylet

Indications for Use (Describe)

The PM2+ System and SmartPICC Stylet is indicated for guidance and positioning of commercially available central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording for catheter guiding and positioning, and intravascular ionic dilution for supplemental catheter navigation. The SmartPICC Stylet, when used with the PM2+ System, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When relying on the patient's ECG signal, the PM2+ System and SmartPICC Stylet is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients. The SmartPICC Stylet is indicated for use with PICC lines having a minimum lumen diameter of 0.021".

Limiting but not contraindicated situations for this technique 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 catheter 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 SmartPICC Stylet
Common Name	Tip Location System
Classification Name	Percutaneous, implanted, long-term intravascular catheter
Regulation Number	21 CFR 880.5870
Product Code(s)	LJS, DRX, DSA

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K200037	Piccolo Medical SmartPICC System	LJS
K240486	PM2 System and ECGuide Connector	LJS
K201286	0.9% Sodium Chloride I.V. Flush Syringe	NGT

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The PM2+ System and SmartPICC Stylet is a device used by clinicians for bedside navigation and tip location confirmation of central venous catheters including PICCs. The PM2+ System and SmartPICC Stylet provide real-time catheter tip location information by using intravascular ECG (ivECG). The SmartPICC Stylet provides intravascular ECG for catheter tip location confirmation as well as an, optional, ionic dilution navigation feature. The SmartPICC Stylet is used only during PICC installation, and removed once the PICC tip position is confirmed to be at the target location. The SmartPICC Stylet is electrically connected to the PM2+ system which processes, displays, and stores the ECG waveforms as well as the ionic dilution data. The PM2+ System is also compatible with the commercially available ECGuide Connector.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The PM2+ System and SmartPICC Stylet is indicated for guidance and positioning of commercially available central venous catheters. The Stylet provides stiffness for use in placement of the catheter, intravascular capability for ECG detection and recording for catheter guiding and positioning, and intravascular ionic dilution for supplemental catheter navigation. The SmartPICC Stylet, when used with the PM2+ System, provides real-time catheter tip location information by using the patient's physiological (cardiac electrical activity and blood flow) information. When relying on the patient's ECG signal, the PM2+ System and SmartPICC Stylet is indicated for use as an alternative method to fluoroscopy or chest x-ray for central venous catheter tip placement confirmation in adult patients. The SmartPICC Stylet is indicated for use with PICC lines having a minimum lumen diameter of 0.021".

Limiting but not contraindicated situations for this technique 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 catheter insertion the use of an additional method is required 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.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device is identical to the predicate K200037 SmartPICC System in its use of intravascular ECG for central venous catheter tip location confirmation as well as its optional ionic dilution navigation feature. In addition, the interaction with the PICC is identical between the two devices. There are minor differences between the packaging configuration, accessories, software system and user interface; however these minor differences do not raise different questions of safety and effectiveness.

The subject device is also equivalent to the additional predicate device (PM2 System with ECGuide Connector). There is a minor change in software between the subject PM2+ and predicate PM2 System and both are used with the same ECGuide Connector disposable component.

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 SmartPICC Stylet verified all device performance requirements including tensile strength, insertion force, corrosion resistance, catheter compatibility, leak testing, infusion rate testing, ionic dilution performance testing, algorithm verification, electrical hardware verification, sterile barrier packaging testing, biocompatibility, electrical safety, EMC, software verification and validation, 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 SmartPICC Stylet 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.