January 22, 2021

Piccolo Medical, Inc.
℅ Allison Kumar
Principal Consultant
Arina Consulting
27 Hilltop Drive
San Carlos, California 94070

Re: K200037
Trade/Device Name: Piccolo Medical SmartPICC System
Regulation Number: 21 CFR 880.5970880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Dated: January 8, 2021
Received: January 12, 2021

Dear Allison Kumar:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jessica Paulsen
Division 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200037

Device Name
Piccolo Medical SmartPICC System

Indications for Use *(Describe)*

The Piccolo Medical SmartPICC System is indicated in adult patients for the positioning of Peripherally Inserted Central Catheters (PICC) with minimum lumen diameter of 0.021". The SmartPICC system provides real-time catheter tip location information by using the patient's cardiac electrical activity (intravascular ECG signal). The SmartPICC system is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients when proper ECG detection is available. The SmartPICC system includes a supplemental intravascular ionic dilution feature that provides qualitative blood flow information to the user to aid catheter navigation.

Note: Use of the intravascular ECG (ivECG) technique to replace x-ray/fluoroscopy confirmation of tip placement is limited, but not contraindicated, for patients where alterations of cardiac rhythm change the presentation of the P-wave such as in atrial fibrillation, atrial flutter, severe tachycardia, pacemaker driven rhythm, and chronic obstructive pulmonary disease (COPD). In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional confirmation method (x-ray or fluoroscopy) 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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510(k) Summary

I. SUBMITTER

Submission Date: December 31, 2019

Submitter Information:

Company: Piccolo Medical, Inc.
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Additional Contacts: Allison Kumar
Arina Consulting, LLC
allison@arinaconsulting.com

II. DEVICE

Trade Name:	SmartPICC System
Common Name:	Accessory to Percutaneous, implanted, long-term intravascular catheter
Device Class:	II
Regulation Number:	880.5970
Product Code:	LJS
Review Panel:	General Hospital

III. PREDICATE DEVICE

Angiodynamics Celerity PICC Tip Positioning Aid (K142889)

Vasonova VPS System (K103255) – Reference Device

IV. INDICATIONS FOR USE

The Piccolo Medical SmartPICC System is indicated in adult patients for the positioning of Peripherally Inserted Central Catheters (PICC) with minimum lumen diameter of 0.021". The SmartPICC system provides real-time catheter tip location information by using the patient's cardiac electrical activity (intravascular ECG signal). The SmartPICC system is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients when proper ECG detection is available. The SmartPICC system includes a supplemental intravascular ionic dilution feature that provides qualitative blood flow information to the user to aid catheter navigation.

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V. DEVICE DESCRIPTION

The Piccolo Medical SmartPICC System is a device used by clinicians for guidance and positioning of commercially available central venous catheters. The reusable SmartPICC System consists of a computer tablet with data processing and display capabilities, a SmartPICC Controller data acquisition module, and a Kit that includes a single use sterile SmartPICC Stylet to enable the use of ivECG confirmation of final PICC tip location by the clinician who is placing the catheter. The SmartPICC System has a supplemental ionic dilution navigation feature to provide qualitative blood flow direction information which requires 5% Dextrose infusion utilizing a mechanical syringe driver, a sterile 20 ml disposable syringe, and tubing with extension set to provide constant flow rate infusion to the SmartPICC Stylet distal tip.

Additional components associated with the reusable system include a USB cable to connect the tablet to the controller and an external ECG (xECG) Trunk Cable to connect the xECG leads to the controller.

Additional accessories in the Stylet Kit include:

- Sterile Drape Clip to secure Stylet hub to sterile patient drape
- Sterile cover for the tablet
- Sterile scissors for opening sterile tubing pouch
- xECG Electrodes and Leads
- Instructions for Use

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Attribute	SUBJECT: Piccolo Medical SmartPICC System	PREDICATE: Angiodynamics Celerity PICC Tip Positioning Aid	Comparison
510K No	K2000037	K142889	
Procode	LJS	LJS	
Date	Pending	February 15, 2015	
Intended Use	Provides real time tip location information of PICC by using ivECG to position PICC in CAJ.	Provides real time tip location information of PICC by using ivECG to position PICC in CAJ.	**SAME**
Operating Principle/ Technology	ivECG for CAJ identification and supplemental ionic dilution feature for qualitative blood flow information	ivECG for CAJ identification	**TECHNOLOGICAL DIFFERENCE**
Alternative to X-ray CAJ Confirmation	Yes - Human Factors/Simulated Use Testing	Yes - Human Factors/Simulated Use Testing	**SAME**
Target Population	Adults 18 and over	Adults 18 and over	**SAME**
Use Environment	Hospital, clinic, skilled nursing, rehab clinic	Hospital, clinic, skilled nursing, rehab clinic	**SAME**
Clinical Use	Single person operation	Single person operation	**SAME**

Discussion of Differences: The SmartPICC differs from the predicate in that the SmartPICC has a supplementary feature that uses ionic dilution to provide qualitative blood flow direction information to the user to aid in catheter navigation. This feature was validated with performance testing and its methodology supported by the reference device and does not raise new questions of safety or effectiveness.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation of the SmartPICC was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing, "' May 1, 1005, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute system toxicity
- Hemolysis

- Thrombogenicity
- Pyrogenicity

The SmartPICC device is considered tissue and blood contacting for a duration of less than 24 hours.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the SmartPICC device. The system complied with the IEC 60601-1 Ed. 3.1_2012 standard for operator and patient safety and EMC in the intended use environment.

Software Verification and Validation Testing and Cybersecurity

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient or operator, either directly or indirectly through incorrect or delayed information or through the action of a care provider.

Cybersecurity was assessed and documented according to the FDA Guidance, "Off-the-shelf Software – Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software."

Mechanical Testing

- Ionic dilution component level and system flow testing
- Leak, Flow, Tensile, Kink, and Torque testing of the stylet
- Syringe driver infusion rate and pressure testing
- ECG (xECG and ivECG) verification testing
- PICC compatibility testing

Packaging and Shelf Life

- Shelf life stability testing
- Environmental conditioning per ASTM D4332
- Packaging verification per ASTM F88 (peel) and ASTM F2096 (bubble leak)

Sterilization Validation:

- Validation performed with EBEAM VDMax25 process per ISO

11137-1, ISO 11137-2, ISO 11137-3

Summary of Human Factors Testing:

Simulated Use / Human Factors Testing was conducted to evaluate the application of the SmartPICC System when used to confirm PICC tip position as an alternative method to chest x-ray or fluoroscopy confirmation. This is the same methodology used by the reference device. The results from the use related studies have been adequately reviewed in order to ensure the safe, effective use of the device for confirmation of tip location of PICC. Based on the content of the proposed SmartPICC Device Hazard Analysis, and the content of the Instructions for Use, the SmartPICC System has demonstrated its suitability for its intended purpose.

Summary of Clinical Testing:

Clinical testing was determined to be not applicable for this 510(k) submission. Bench testing was sufficient to demonstrate substantial equivalence of the Smart PICC System to the predicate device.

VIII. CONCLUSIONS:

The non-clinical data support the safety of the device and the software verification and validation demonstrate that Piccolo Medical's SmartPICC System should perform as intended in the specified use conditions, and which are substantially equivalent to the predicate device that is currently marketed for the same intended use.