October 20, 2021

Abaxis, Inc.
Julie Schoell
Director, Regulatory Affairs
3240 Whipple Road
Union City, California 94587

Re: K200865
Trade/Device Name: Piccolo® Potassium Test System
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium Test System
Regulatory Class: Class II
Product Code: MZV
Dated: April 2, 2021
Received: April 6, 2021

Dear Julie Schoell:

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 and Part 809); 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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*

k200865

Device Name
Piccolo® Potassium Test System

Indications for Use *(Describe)*

The Piccolo® Potassium Test System, used with the Piccolo® blood chemistry analyzer or the Piccolo Xpress® chemistry analyzer, is intended to be used for the in vitro quantitative determination of potassium, in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

The potassium assay is used for the quantitation of potassium in human heparinized whole blood, heparinized plasma, or serum. Potassium measurements are used in the diagnosis and treatment of renal glomerular or tubular disease, adrenocortical insufficiency, diabetic ketoacidosis, excessive intravenous potassium therapy, sepsis, panhypopituitarism, in vitro hemolysis, hyperaldosteronism, malnutrition, hyperinsulinism, metabolic alkalosis and gastrointestinal loss.

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

This section provides a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

510(k) Number:	K200865
510(k) Owner:	Abaxis Inc.
Submitter/ Contact Person:	Julie Schoell Manager II Attention: Abaxis Inc 3240 Whipple Road Union City, CA 94587 Phone: 269-312-2922
Date prepared:	October 15, 2021

II. DEVICE

Trade Name:	Piccolo® Potassium Test System
Common or Usual name:	Test, System, Potassium, Enzymatic Method
Classification name:	Potassium test system (21 CFR 862.1600)
Regulatory Class:	Class II
Product Code:	MZV

III. PREDICATE DEVICE

Primary Predicate: Piccolo® Potassium Test System (included on Piccolo MetLyte 7 Reagent Panel) (K992140)

The Siemens Dimension Vista® Integrated System (including the Potassium ISE Test) (K051087) was used as the comparative method.

IV. SUBMISSION/DEVICE OVERVIEW

This submission is a Dual 510(k) and CLIA Waiver by Application (Dual Submission) for a modification to a previously cleared device – modification to the Piccolo® Potassium Test run on the Piccolo Xpress® chemistry analyzer.

Device Description

The Piccolo® Potassium Test System is a single-use, disposable system used with the Piccolo Xpress® chemistry analyzer for the in vitro quantitative determination of potassium in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location. The Piccolo® Potassium Test System is designed to separate a heparinized whole blood sample into plasma and blood cells. The disc meters the required quantity of plasma and diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer. Alternatively, the disc may also be used with serum.

The Piccolo Xpress® chemistry analyzer (previously cleared under K942782) is a portable clinical chemistry system designed to run only Piccolo test rotors. The instrument interacts with the rotor to move fluid across the sensors and generate quantitative results. Specimens are identified by scanning a barcode or by manually entering the information via the touchscreen. The Piccolo Xpress® chemistry analyzer has slots to accommodate the cartridges discs. The analyzer will determine the configuration of the system by detecting which discs are installed.

The Piccolo® Potassium Test System will be used with previously cleared rotor systems in a clinical laboratory setting or point-of-care location.

V. INDICATIONS FOR USE

Intended Use:

The Piccolo® Potassium Test System, used with the Piccolo® blood chemistry analyzer or the Piccolo Xpress® chemistry analyzer, is intended to be used for the in vitro quantitative determination of potassium, in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Potassium: The potassium assay is used for the quantitation of potassium in human heparinized whole blood, heparinized plasma, or serum. Potassium measurements are used in the diagnosis and treatment of renal glomerular or tubular disease, adrenocortical insufficiency, diabetic ketoacidosis, excessive intravenous potassium therapy, sepsis,

panhypopituitarism, in vitro hemolysis, hyperaldosteronism, malnutrition, hyperinsulinism, metabolic alkalosis and gastrointestinal loss.

The Indications for Use statement for the Subject device is identical to the Primary predicate device Piccolo® Potassium Test System (included on Piccolo MetLyte 7 Reagent Panel) (K992140).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Piccolo® Potassium Test is compared to its predicate device for substantial equivalence based on the following criteria:

A. Principle of Operation
B. Technological and Performance Characteristics

A. Principle of Operation

The principle of operation or principle of analysis of the Piccolo® Potassium Test is the same as the predicate which is based on the assay method (e.g., enzymatic), assay calibration, and mode of detection (e.g., photometric).

B. Technological and Performance Characteristics

The Piccolo® Potassium Test device and the predicate Piccolo® Potassium Test System (K992140) are based on the following technological elements:

Table 1. Comparison of Subject and Predicate Device Technological Features

Characteristic	**Piccolo® Potassium Test System (Subject Device)**	**Piccolo® Potassium Test System** (included on Piccolo MetLyte 7 Reagent Panel) **(K992140) (Predicate Device)**
Principle of Operation/Methodology	Enzymatic colormetric assay	Enzymatic colormetric assay
Sample Type	Heparinized venous whole blood, heparinized plasma, and serum	Heparinized venous whole blood, heparinized plasma, and serum
Dynamic Range	1.5 – 8.5 mmol/L	1.5 – 8.5 mmol/L
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Bar code with factory calibrated lot specific data
Testing Environment	Professional use	Professional use
Sample Size	Approximately 100 µL	Approximately 100 µL

VII. PERFORMANCE DATA

Performance testing was completed to demonstrate that the Piccolo® Potassium Test System is substantially equivalent in performance and safety and efficacy to the predicate Piccolo Potassium Test System (included on Piccolo MetLyte 7 Reagent Panel) (K992140).

(The analytical performance for the associated rotor panel analytes have been previously established in K934592, K993211, K010670, K022312, K040115, K091052, K051108, K130113, K950164, K942782, K992140.)

Performance Testing

Performance testing was performed to demonstrate the accuracy of the potassium test on the Piccolo Xpress® chemistry analyzer by a method comparison study for agreement with the comparative method device.

Analytical Performance

1. Precision

The precision testing was based on CLSI document EP05-A3: *Evaluation of Precision of Quantitative Measurement Procedures*.

The precision of the Piccolo Potassium Test System was evaluated at a CLIA waived site with three analyzers, one lot of reagent discs, over five days. Total precision and within-run were estimated for each level. The results of the study are shown in Table 2.

Table 2. Precision Summary of Piccolo Potassium Test System - Plasma

Sample	Average mmol/L	Within Run SD	Within Run %CV	Total SD	Total %CV
Control 1	3.22	0.09	2.79	0.11	3.28
Control 2	6.19	0.09	1.38	0.10	1.65
Plasma Pool 1	3.22	0.07	2.31	0.09	2.89
Plasma Pool 2	5.42	0.09	1.58	0.10	1.89

Whole blood precision was tested at a CLIA waived site by two CLIA waiver operators. The study used four Piccolo Xpress Analyzers with 16 replicates per sample for four (4) fresh, lithium heparin whole blood samples.

Table 3. Whole Blood Precision (Each sample is N = 16)

			Repeatability (Within-Run)		Between-Operator		Between-Analyzer		Total	
Sample	N	Average K+ mmol/L	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Whole Blood 1	16	3.9	0.06	1.6	0.02	0.4	0.09	2.2	0.11	2.8
Whole Blood 2	16	4.0	0.11	2.9	0.00	0.0	0.07	1.9	0.14	3.4
Whole Blood 3	16	4.0	0.11	2.8	0.03	0.9	0.10	2.5	0.15	3.9
Whole Blood 4	16	4.0	0.11	2.7	0.02	0.6	0.08	1.9	0.13	3.4

2. Linearity

The study was designed based on CLSI EP06-A: *Evaluation of the linearity of quantitative measurement procedures*.

The linearity of Piccolo Potassium Test System on the Piccolo Xpress® chemistry analyzer was evaluated by preparing whole blood, serum, and plasma samples of varying analyte levels that spanned the reportable range of the tests. The Piccolo Potassium Test System demonstrated linearity over the reportable range as shown in Table 4. Regression Parameter Estimates.

For all three matrices and various concentration ranges tested, the deviation from linearity (DL) estimate was within +/- 0.31, the repeatability test resulted in RMSE estimates <= 0.32, and the R-square estimates were all > 0.98, thus satisfying the conditions of linearity as per the CLSI EP-06A guidance.

The DL estimates are within the current CLIA accuracy goal for potassium per 42 CFR 493.931, which identifies a target value of ± 0.5 mmol/L for acceptable performance and supports linearity for all three matrices for the current dynamic range of 1.5 to 8.5 mmol/L.

Table 4. Regression Parameter Estimates from CLSI Linear Model Fit

Sample Type	Reportable Range mmol/L	Range Tested, mmol/L	R-square	Slope (95% CI)	Intercept (95% CI)
Whole Blood	1.5 – 8.5	1.2 to 8.5	0.987	0.985	0.075
Plasma	1.5 – 8.5	1.2 to 8.5	0.995	0.972	0.032
Serum*	1.5 – 8.5	1.0 to 9.5	0.995	1.002 (0.914 to 1.091)	-0.128 (-0.577 to 0.321)

* Weighted Deming Regression Analysis

3. Limit of Quantitation (LoQ)

The study was based on the CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*.

The LoQs of the Piccolo Potassium Test System were evaluated on the Piccolo Xpress® chemistry Analyzer using whole blood, plasma and serum prepared by taking a native blood sample of known K+ concentration and diluting it to the target concentration using dialyzed (K+ free) serum/plasma as the diluent concentrations and two reagent disc lots, four low level samples of known measurand concentration, across a minimum of three days. The LoQs for the Piccolo Potassium Test System were determined to be 1.5 mmol/L.

Comparison Study

4. Method Comparison

Method comparison was demonstrated in a study comparing the Piccolo Potassium Test System performance on the Piccolo Xpress® chemistry analyzer to the Siemens VISTA ISE (K051087) comparative method. Correlation studies were conducted at two sites. Site 1 tested heparinized whole blood, heparinized plasma, and serum. Site 2 tested only fresh heparinized whole blood on the Abaxis analyzer. Whole blood, serum, and plasma were evaluated and analyzed on the Piccolo Xpress® chemistry analyzer against plasma and serum specimens on the Siemens VISTA ISE. A Deming linear regression analysis was performed. Results are presented in Table 5.

Table 5. Method Comparison Results

Site 1 – Moderately Complex Site				
Sample Type	**N**	**Slope**	**Intercept**	**R^2**
Whole Blood	178	0.98	0.12	0.969
Plasma	178	0.98	0.03	0.979
Serum	178	0.98	0.06	0.979
Site 2 – Waived Site				
Whole Blood	130	0.99	0.13	0.969

The results of the testing demonstrated the accuracy of the potassium test on the Piccolo Xpress® chemistry analyzer with the comparative method device. The results of the testing

confirmed that subject device performs substantially equivalent to the predicate device Piccolo® Potassium Test System (included on Piccolo MetLyte 7 Reagent Panel) (K992140).

VIII. CONCLUSIONS

The results of the performance and clinical data demonstrate the Piccolo® Potassium Test System will perform as intended in the specified use conditions. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.