

Sample Type Comparison:

A study was conducted to compare venous whole blood and serum run on the Piccolo® Point-of-Care Chemistry Analyzer.

Serum and whole blood comparability were established for sodium.

8. Conclusions

The clinical and non-clinical tests performed using the Piccolo Sodium Test System (contained on the Piccolo MetLyte 7 Reagent Disc) demonstrate that the device is as safe, effective and performs as well as the legally marketed predicate device identified above.

OCT 25 1999

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K993211

1. Applicant Information:

Date Prepared: September 23, 1999
Name: Abaxis, Inc.
Address: 1320 Chesapeake Drive
Sunnyvale, CA 94089

Contact Person: Lisa G. McGrath
Phone Number: (408) 745-6880
Fax Number: (408) 734-2874

2. Device Information:

Classification: Class II
Trade Name: Piccolo® Sodium Test System

Classification Name: Sodium test system 862.1665

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Product Name	Manufacturer	Device Number	Date of Sale
KNA™ 2 Sodium-Potassium Analyzer	Radiometer America, Inc.	K830805	4/8/83

4. Description of the Device:

The Piccolo Sodium Test System (contained on the Piccolo MetLyte 7 Reagent Disc) 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

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perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer. Alternately, the disc may also be used with serum.

5. Statement of Intended Use:

The Piccolo® MetLyte 7 Reagent Disc (contains Piccolo Sodium Test System) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of sodium in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 outlines the technological characteristics of the Piccolo Sodium Test System in comparison to the legally marketed predicate device.

Table 1 : Specification Comparison: Piccolo Sodium Test System

	Piccolo Point-of-Care Chemistry Analyzer	Radiometer KNA™ 2 Sodium-Potassium Analyzer
Intended Use	quantitative analysis of sodium	quantitative determination of sodium
Methodology	enzymatic activation	ion-selective electrodes
Sample Type	whole blood, plasma, serum	whole blood, plasma, serum, urine
Sensitivity	2.8 (Δ mA/min)/(mmol/L)	3.1 (mmol/L)/(mV)
Reagents	dry, test specific reagent beads	N/A
Temperature	37° C	37° C
Calibration	bar code with disc-specific calibration data	automatic 1 point calibration every 2 hours; 2 point calibration every 8 hours
Reference Range: 135-145 mEq/L		
Assay Range	110 - 170 mmol/L	7 - 350 mmol/L
Accuracy:		
Sample size (n)	113	
Corr. Coefficient	0.937	
Slope	0.782	
Intercept	27.70	
SEE	3.79	
R-Square	0.878	

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7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Table 2 summarizes the results of clinical and non-clinical tests performed using the Piccolo® Sodium Test System.

Linearity:

Data for sodium were found to be statistically linear at the 99% significance level by the F-test.

**Table 2
Summary of Linearity**

	Sodium
F-Ratio	0.99
Slope	0.99
Intercept	-1.00
Corr. Coefficient	1.00

99% Critical F 2.99

Precision:

Precision studies were designed to evaluate within-run and total precision of sodium included on the Piccolo MetLyte 7 Reagent Disc when run on the Piccolo Point-of-Care Chemistry Analyzer.

**Table 3:
Within-Run and Total Precision of Sodium Run
on the Piccolo Point-of-Care Chemistry Analyzer^A**

	Within-Run (n = 80)	Total (n= 80)
<u>Moni-Trol 1</u>		
Mean	144	144
SD	2.3	2.3
CV	1.6	1.6
<u>Moni-Trol 2</u>		
Mean	120	120
SD	2.1	2.1
CV	1.8	1.8

^A Results pooled from 4 instruments each running 20 discs.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 1999

Ms. Lisa G. McGrath
Regulatory Affairs Specialist
Abaxis
1320 Chesapeake Terrace
Sunnyvale, California 94089

Re: K993211
Trade Name: Piccolo® Sodium Test System
Regulatory Class: II
Product Code: JGS
Dated: September 23, 1999
Received: September 24, 1999

Dear Ms. McGrath:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

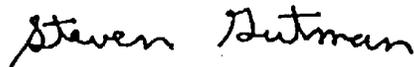
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K993211

Device Name: **Piccolo® Sodium Test System**

Intended Use:

The Piccolo Sodium Test System (contained on the MetLyte 7 Reagent Disc), used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of sodium in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

The sodium assay is used for the quantitation of sodium in human heparinized whole blood, heparinized plasma, or serum. Sodium measurements are used in the diagnosis and treatment of dehydration, diabetes insipidus, loss of hypotonic gastrointestinal fluids, salt poisoning, selective depression of sense of thirst, skin losses, burns, sweating, hyperaldosteronism, CNS disorders, dilutional, depletional and delusional hyponatremia and syndrome of inappropriate ADH secretion.

Sean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Science
510(k) Number K993211

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)