AUG 26 1999

K992140

APPENDIX E 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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ABAXIS

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: _____

1. Applicant Information:

Date Prepared:	June 22, 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:	Creatine Kinase, Potassium and Total Carbon Dioxide test systems included on the Piccolo MetLyte 7 Reagent Disc

Classification Name:

Bicarbonate/Bicarbonate test system	862.1160
Creatinine Kinase test system	862.1215
Potassium test system	862.1600

(Substantial equivalence for creatinine kinase, glucose and urea nitrogen, which are test systems included on the Piccolo MetLyte 7 Reagent Disc, were established previously in K934592 and K942782, therefore these test systems are not included in this summary.)

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:

Subject Device	Predicate Device			
	Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Piccolo® Potassium Test System	KNA™ 2 Sodium-Potassium Analyzer	Radiometer America, Inc.	K830805	4/8/83
Piccolo Creatine Kinase and Total Carbon Dioxide Test System	Roche Reagents for carbon dioxide and creatine kinase on the COBAS FARA™ Chemistry System	Roche Diagnostic Systems, Inc.	CK: K834502 CO_2 K844987	2/27/84 1/18/85

4. Description of the Device:

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 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 run on the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of creatine kinase, creatinine, glucose, potassium, total carbon dioxide and urea nitrogen 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:

Tables 1 - 3 outline the technological characteristics of the Piccolo MetLyte 7 Reagent Disc (for creatine kinase, potassium and total carbon dioxide) in comparison to those of the legally marketed predicate devices.

Table 1: Specification Comparison Creatine Kinase Test System

	Piccolo® Point-of-Care Chemistry Analyzer	**COBAS FARA™ Chemistry System**
Intended Use	quantitative analysis of creatine kinase	quantitative determination of creatine kinase
Methodology	isoenzymes	isoenzymes
Sample Type	whole blood, plasma, serum	serum
Sensitivity	0.0001 A/min/U/L	0.0001 A/min/U/L
Reagents	dry test-specific reagent beads	liquid mono reagent
Temperature	37°C	37°C
Calibration	bar code with disc-specific calibration data	pre-set calibration
Assay Range	5 - 5,000 U/L	0 - 2,000 U/L
Performance Characteristics		
Accuracy:		
Sample size (n)	47	
Range of Samples Tested	6.2 - 813.2	
Corr. Coefficient	0.967	
Slope	1.194	
Intercept	-24.983	
SEE	9.050	
R-Square	0.934	

Table 2: Specification Comparison: Potassium Test System

	Piccolo Point-of-Care Chemistry Analyzer	**Radiometer KNA™ 2 Sodium-Potassium Analyzer**
Intended Use	quantitative analysis of potassium	quantitative determination of potassium
Methodology	enzymatic activation	ion-selective electrodes
Sample Type	whole blood, plasma, serum	whole blood, plasma, serum, urine
Sensitivity	0.024 A/min/mmol/L	0.58 (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
Performance Characteristics		
Assay Range	1.5 - 8.5 mmol/L	1.0 - 99.9 mmol/L
Accuracy:		
Sample size (n)	58	
Range of Samples Tested	2.0 - 6.8	
Corr. Coefficient	0.969	
Slope	0.863	
Intercept	0.573	
SEE	0.141	
R-Square	0.939	

Table 3: Specification Comparison: Total Carbon Dioxide Test System

	Piccolo® Point-of-Care Chemistry Analyzer	COBAS FARA™ Chemistry System
Intended Use	quantitative analysis of total carbon dioxide	quantitative determination of total carbon dioxide
Methodology	enzymatic	enzymatic using phos-phoenol pyruvate carbo-xylase and malate de-hydrogenase
Sample Type	whole blood, plasma, serum	serum and plasma
Sensitivity	0.0037 A/min/mmol/L	0.0427 A/mmol/L
Reagents	dry test-specific reagent beads	liquid substrate reagent 1 and liquid enzyme reagent 2
Temperature	37° C	37° C
Calibration	bar code with disc-specific calibration data	Roche calibrator serum every 6 months
Performance Characteristics		
Assay Range	5 - 40 mmol/L	0 - 40 mmol/L
Accuracy:		
Sample size (n)	60	
Range of Samples Tested	6.1 -38.5	
Corr. Coefficient	0.947	
Slope	0.903	
Intercept	2.444	
SEE	0.837	
R-Square	0.900	

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

Tables 4 - 5 summarize the results of clinical and non-clinical tests performed using the Piccolo MetLyte 7 Reagent Disc.

Linearity:

Data for creatine kinase, potassium and total carbon dioxide were found to be statistically linear at the 99% significance level by the F-test.

Table 4: Summary of Linearity

	Creatine Kinase	Potassium	Total Carbon Dioxide
F-Ratio	0.11	0.37	0.88
Slope	1.00	1.05	1.09
Intercept	-7.45	0.03	-0.71
Corr. Coefficient	1.00	1.00	0.97

(99% Critical F 2.99)

Precision:

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

Table 5:
Within-Run and Total Precision for Creatine Kinase, Potassium and Total Carbon Dioxide Run on the Piccolo Point-of-Care Chemistry Analyzer [A]

Analyte	Within-Run (n = 120)	Total (n= 120)
Creatine Kinase (U/L)		
Moni-Trol 1	134	134
SD	2.7	2.7
CV	2.0	2.0
Moni-Trol 2		
Mean	526	526
SD	7.7	7.7
CV	1.5	1.5
Potassium (mmol/L)		
Moni-Trol 1		
Mean	6.1	6.1
SD	0.32	0.35
CV	5.2	5.7
Moni-Trol 2		
Mean	4.1	4.1
SD	0.24	0.26
CV	5.9	6.3
Total Carbon Dioxide (mmol/L)		
Moni-Trol 1		
Mean	21	21
SD	2.29	2.29
CV	10.7	10.7
Moni-Trol 2		
Mean	10	10
SD	0.90	0.90
CV	8.6	8.6

[A] Results pooled from 6 instruments each running 20 discs.

Sample Type Comparison:

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

Serum and whole blood comparability were established for each analyte and serum, whole blood and finger stick comparability were established for creatine kinase when run on the Piccolo Point-of-Care Chemistry Analyzer.

8. Conclusions

The clinical and non-clinical tests performed for creatine kinase, potassium and total carbon dioxide when run on the Piccolo Point-of-Care Chemistry Analyzer demonstrate that the test systems are as safe, effective and performs as well as the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 26 1999

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

Re: K992140
Trade Name: Piccolo® MetLyte 7 Reagent Disc
Regulatory Class: I reserved
Product Code: JLB
Dated: June 22, 1999
Received: June 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.

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 Gutman

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): K992140

Device Name: **Piccolo® MetLyte 7 Reagent Disc**

Intended Use:

The Piccolo 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 creatine kinase, creatinine, glucose, potassium, total carbon dioxide and urea nitrogen in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Creatine Kinase The creatine kinase assay is used for the quantitation of creatine kinase in human heparinized whole blood, heparinized plasma, or serum. Measurements of creatine kinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction, progressive muscular dystrophy, dermatomyositis, rhabdomyolysis due to drug ingestion, hyperosmolality, autoimmune disease, delirium tremens, convulsions, Crush syndrome, hypothyroidism, surgery, severe exercise, intramuscular injection, physical inactivity, decreased muscle mass.

Creatinine The creatinine assay is used for the quantitation of creatinine in human heparinized whole blood, heparinized plasma, or serum. Creatinine measurements are used in the diagnosis and treatment of renal diseases and monitoring of renal dialysis.

Glucose The glucose assay is used for the quantitation of glucose in human heparinized whole blood, heparinized plasma, or serum. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders, including adult and juvenile diabetes mellitus and hypoglycemia.

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.

Total Carbon Dioxide The total carbon dioxide assay is used for the quantitation of total carbon dioxide in human heparinized whole blood, heparinized plasma, or serum. Total carbon dioxide measurements are used in the diagnosis and treatment of primary MetLyte 7 alkalosis and acidosis and primary respiratory alkalosis and acidosis.

Indications for Use, Page 2

Urea Nitrogen The urea nitrogen assay is used for the quantitation of urea nitrogen in human heparinized whole blood, heparinized plasma, or serum. Urea nitrogen measurements are used in the diagnosis and treatment of renal and MetLyte 7 diseases.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over- The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)