SEP 5 2002

3240 Whipple Road, Union City, CA 94587
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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: K022312

1. Applicant Information:

Date Prepared:	July 15, 2002
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Robert Milder
Phone Number:	(510) 675-6524
Fax Number:	(510) 441-6150

2. Device Information:

Classification	Class I
Trade Name:	Piccolo® Phosphorus Test System
Classification Name:	Phosphorus (Inorganic) Test system 862.1580

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:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Phosphorus Slides on the Vitros 950 Chemistry System	Johnson and Johnson Clinical Diagnostics	K932729	8/3/93

Summary of Safety and Effectiveness,

4. Description of the Device:

The Piccolo Renal Function Panel Reagent Disc (which contains the Piccolo Phosphorus 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. Alternately, the disc may also be used with serum.

5. Statement of Intended Use:

The Piccolo Renal Function Panel Reagent Disc (contains the Piccolo Phosphorus Test System) use with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of phosphorus 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 Phosphorus Test System in comparison to the legally marketed predicate device.

Table 1: Specification Comparison: Piccolo Phosphorus Test System

	Piccolo Point-of-Care Chemistry Analyzer	**Vitros 950 Chemistry System**
Intended Use	Quantitative analysis of phosphorus	Quantitative analysis of phosphorus
Methodology	Enzymatic endpoint reaction	Colorimetric
Sample Type	Heparinized whole blood, heparainized plasma and serum	Heparinized plasma, serum and urine
Sensitivity	0.2 mg/dL	0.5 mg/dL
Reagents	Dry test-specific reagent beads	*p*-Methylaminophenol sulfate and ammonium molybdate
Temperature	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	0.2 - 20 mg/dL	0.5 – 13.0 mg/dL
Testing Environment	Professional use	Professional use
Sample Size	100 µL	10 µL

Summary of Safety and Effectiveness,

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

Tables 2 summarize the results of clinical and non-clinical tests performed using the Piccolo® Phosphorus Test System.

Linearity:

Table 2:
Summary of Linearity

	Phosphorus
Slope	1.00
Intercept	+0.2
Corr. Coefficient	0.999
Sample Range	2 - 17 mg/dL

Precision:

Precision studies were designed to evaluate within-run and total precision of phosphorus included on the Piccolo Renal Function Panel Reagent Disc when run on the Piccolo Point-of-Care Chemistry Analyzer.

Table 3:
Within-Run and Total Precision for Phosphorus,
Assayed on the Piccolo Point-of-Care Chemistry Analyzer

Analyte	Within-Run (n = 80)	Total (n = 80)
Phosphorus (mg/dL)		
Level 1		
Mean	3.1	3.1
SD	0.12	0.14
CV	3.7	4.7
Level 2		
Mean	7.3	7.3
SD	0.09	0.15
CV	1.3	2.0

Summary of Safety and Effectiveness,

Sample Type Comparison:

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

Serum, heparinized plasma and heparinized whole blood comparability were established for phosphorus. Phosphorous concentrations in serum are 0.3 mg/dL higher than in heparinized plasma and heparinized whole blood.

8. Conclusions

The clinical and non-clinical tests performed for phosphorus, when run on the Piccolo Point-of-Care Chemistry Analyzer demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 5 2002

Mr. Robert Milder
Chief of Operations Officer
Abaxis Inc.
3240 Whipple Road
Union City, CA 94587

Re: k022312
Trade/Device Name: Piccolo® Phosphorus Test System
Regulation Number: 21 CFR 862.1580
Regulation Name: Phosphorus (inorganic) Test System
Regulatory Class: Class I
Product Code: CEO
Dated: July 15, 2002
Received: July 17, 2002

Dear Mr. Milder:

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. 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 (PMA), 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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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

12.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K022312

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

Intended Use:

The Piccolo Phosphorus Test System (presently contained on the Renal Function Panel Reagent disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of phosphorus in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Phosphorus The phosphorus assay is used for the quantitiation of phosphorus in human heparinized whole blood, heparinized plasma or serum. Phosphorus measurements are used in the diagnosis and treatment of renal insufficiency, hypoparathyroidism, vitamin D imbalance, a high calcium diet, hyperparathyroidism, and insulin treatment of diabetic ketacidosis.

(Division Sign-Off)
Division of Clinical Labora
510(k) Number K022312

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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