

JAN 24 2003

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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: K023642

### 1. Applicant Information:

Date Prepared: October 29, 2002  
Name: Abaxis, Inc.  
Address: 3240 Whipple Road  
Union City, CA 94587

Contact Person: Dennis M. Bleile, PhD  
Phone Number: (510) 675-6515  
Fax Number: (510) 441-6150

### 2. Device Information:

Classification: Class I  
Trade Name: Piccolo® Total Cholesterol Test System

Classification Name: Total Cholesterol Test system 862.1175

### 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
Cholesterol Assay-RA	Bayer Diagnostics	K802743*  (Ames Sera-Pak Cholesterol Reagent Kit)	12/10/80

\* Presumptive K number. NOTE: The predicate device is currently known as Bayer Diagnostics Cholesterol Reagent. Since Bayer has undergone a series of mergers and other business transactions (e.g., Bayer, Technicon, Miles, Ames), the exact regulatory "lineage" is difficult to determine.

**Summary of Safety and Effectiveness (continued)****4. Description of the Device:**

The Piccolo® Lipid Panel Reagent Disc (which contains the Piccolo® Total Cholesterol 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® Lipid Panel Reagent Disc (contains the Piccolo® Total Cholesterol Test System) use with the Piccolo® Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of total cholesterol 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® Total Cholesterol Test System in comparison to the legally marketed predicate device.

**Summary of Safety and Effectiveness (continued)****Table 1: Specification Comparison for Piccolo Total Cholesterol (CHOL) Test System versus Bayer Cholesterol-RA Assay**

	<b>Piccolo Cholesterol Assay on Abaxis Point-of-Care Chemistry Analyzer</b>	<b>Bayer Cholesterol-RA Assay on Hitachi 917 Analyzer</b>
<b>Intended Use</b>	Quantitative analysis of cholesterol	Quantitative analysis of cholesterol
<b>Methodology</b>	Enzymatic endpoint reaction	Enzymatic endpoint reaction
<b>Sample Type</b>	Heparinized whole blood, heparinized plasma, and serum	Heparinized plasma and serum
<b>Sensitivity</b>	0.00294 A per mg/dL or 0.113 A per mmol/L; 20 mg/dL	0.0012 A per mg/dL or 0.0462 A per mmol/L
<b>Reagents</b>	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Dry reagents (reconstituted by user prior to use) and liquid reagents
<b>Temperature of Reaction</b>	37°C	37°C
<b>Calibration</b>	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
<b>Assay Range</b>	20 - 520 mg/dL	0 – 500 mg/dL
<b>Testing Environment</b>	Professional use	Professional use
<b>Sample Size</b>	Approx 100 µL	2.7 µL

**7. Brief Discussion of the Clinical and Nonclinical Tests Relied on for a Determination of Substantial Equivalence.**

The following information summarizes the results of clinical and non-clinical tests performed using the Piccolo® Total Cholesterol Test System.

**Summary of Safety and Effectiveness (continued)****Linearity:****Table 2: Summary of Linearity**

	Total Cholesterol
<b>Slope</b>	0.989
<b>Intercept</b>	19.7
<b>Correlation Coefficient (r)</b>	0.999

**Precision:**

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

**Table 3: Within-Run and Total Precision of Total Cholesterol Assayed on the Piccolo® Point-of-Care Chemistry Analyzer**

	Within-Run (n =160)	Total (n =160)
<b>Total Cholesterol (mg/dL)</b>		
<u>Serum 1</u>		
Mean	223.7	223.7
SD	3.0	5.7
%CV	1.3	2.6
<u>Serum 2</u>		
Mean	202.2	202.2
SD	3.1	4.4
%CV	1.5	2.2

**Summary of Safety and Effectiveness (continued)****Sample Type Comparison:**

A study was conducted to examine and compare serum, heparinized plasma, and heparinized whole blood the Piccolo® Point-of-Care Chemistry Analyzer. The study included samples from 20 different patients. Each sample type was tested in quadruplicate. Serum, heparinized plasma and heparinized whole blood comparability was established for total cholesterol.

**Method Comparison:**

**Table 4: Method Comparison Data for Total Cholesterol Assayed on the Using the Abaxis Piccolo® CHOL Assay and the Bayer CHOL Assay**

	Parameters	Statistics
Piccolo CHOL Test System	n*	174
Bayer Cholesterol Assay	n*	174
Piccolo CHOL Test System	Mean	202.0
Bayer Cholesterol Assay	Mean	203.1
Piccolo CHOL Test System	Std. Dev.	53.5
Bayer Cholesterol Assay	Std. Dev.	49.4
Piccolo CHOL Test System	Range of Samples	108 - 342
Bayer Cholesterol Assay	Range of Samples	115 - 342

	Linear Regression	Deming Regression
n*	174	174
Slope	1.079	1.083
Intercept	-17.1	-17.9
Correlation Coefficient (r)	0.997	0.997
Std. Error of the Estimate (SEE)	4.5	N/A

\* n = all data points (patient samples were run in duplicate and both values were plotted; number of patient samples = n/2)

**8. Conclusions**

The clinical and non-clinical tests performed using the Piccolo® Total Cholesterol Test System, 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

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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Dennis M. Bleile, Ph.D.  
Director of Assay Development  
Abaxis, Inc.  
3240 Whipple Road  
Union City, CA 94587

JAN 24 2003

Re: k023642  
Trade/Device Name: Piccolo<sup>®</sup> Total Cholesterol Test System  
Regulation Number: 21 CFR 862.1175  
Regulation Name: Cholesterol (total) test system  
Regulatory Class: Class I  
Product Code: CHH  
Dated: October 29, 2002  
Received: October 30, 2002

Dear Dr. Bleile:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

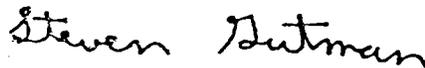
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K023642

Device Name: Piccolo® Total Cholesterol Test System

Intended Use:

The Piccolo Total Cholesterol Test System used with the Piccolo Point-of-Care Chemistry Analyzer is intended for the *in vitro* quantitative determination of total cholesterol in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein disorders.

(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)

Don D Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K023642