JAN 2 4 2003

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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: K023640

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® HDL Test System
Classification Name:	HDL Test system 862.1475

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**
HDL-C plus (HDL assay) Run on a Hitachi 917 Clinical Chemistry Analyzer	Roche Diagnostics	K902935* (Roche Cobas Ready HDL Reagent)	9/27/90

* Presumptive K number. NOTE: The predicate device is currently known as HDL-C plus, for use on Hitachi instrumentation. Since Roche and Hitachi have a co-marketing agreement, it is assumed that this submission (for the Cobas) is the predicate.

Summary of Safety and Effectiveness (continued)

4. Description of the Device:

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

Summary of Safety and Effectiveness (continued)

Table 1: Specification Comparison for Piccolo HDL (HDL) Test System versus Roche HDL-RA Assay

	Piccolo HDL Assay on Abaxis Point-of-Care Chemistry Analyzer	Roche Diagnostics HDL-C plus Assay on Hitachi 917 Analyzer
Intended Use	Quantitative analysis of HDL	Quantitative analysis of HDL
Methodology	Hybrid enzymatic colorimetric end-point test, making use of dextran/sulfate precipitation, centrifugation, and PEG-modified enzymes	Homogeneous enzymatic colorimetric end-point test, making use of dextran/sulfate suspension and PEG-modified enzymes
Sample Type	Heparinized whole blood, heparinized plasma, and serum	Heparinized plasma and serum
Sensitivity	0.00799 A per mg/dL or 0.309 A per mmol/L; 15 mg/dL	3 mg/dL
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid reagents
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	15 – 100 mg/dL	3 - 120 mg/dL
Testing Environment	Professional use	Professional use
Sample Size	Approx 100 µL	3 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® HDL Test System.

Summary of Safety and Effectiveness (continued)

Linearity:

Table 2: Summary of Linearity

	HDL
Slope	0.983
Intercept	0.5
Correlation Coefficient (r)	0.997

Precision:

Precision studies were designed to evaluate within-run and total precision of HDL 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 HDL Assayed on the Piccolo® Point-of-Care Chemistry Analyzer

	Within-Run (n =160)	Total (n =160)
HDL (mg/dL)		
Serum 1		
Mean	55.3	55.3
SD	1.4	1.9
%CV	2.6	3.5
Serum 2		
Mean	38.0	38.0
SD	1.3	1.6
%CV	3.5	4.3

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 HDL.

Method Comparison:

Table 4: Method Comparison Data for HDL Assayed on the Using the Abaxis Piccolo® HDL Assay and the Roche HDL Assay

	Parameters	Statistics
Piccolo CHOL Test System	n*	166
Roche HDL Assay	n*	166
Piccolo HDL Test System	Mean	53.2
Roche HDL Assay	Mean	52.8
Piccolo HDL Test System	Std. Dev.	15.1
Roche HDL Assay	Std. Dev.	17.1
Piccolo HDL Test System	Range of Samples	25 - 90
Roche HDL Assay	Range of Samples	23 - 97

	Linear Regression	Deming Regression
n*	166	166
Slope	0.851	0.877
Intercept	8.3	6.9
Correlation Coefficient (r)	0.965	0.965
Std. Error of the Estimate (SEE)	3.9	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® HDL 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

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 4 2003

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

Re: k023640
Trade/Device Name: Piccolo® HDL Test System
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: LBS
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).

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,

Steven Gutman

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): K023640

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

Intended Use:

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

Indications for Use:

Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal 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)

K023640 for Dr. Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023640