3240 Whipple Road, Union City, CA 94587
Phone 510 • 675-6500 Fax 510 • 441-6150

ABAXIS

FEB 15 2013

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: K130200

1. Applicant Information:

Date Prepared:	February 8, 2013
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) 405-8871

2. Device Information:

Classification	Class I- Reserved (point-of-care)
Trade Name:	Piccolo® Total Cholesterol –Capillary 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**
Cobas Cholesterol Gen.2	Roche Diagnostics Indianapolis, IN	K031824	7/09/2003

Summary of Safety and Effectiveness (continued)

4. Description of the Device:

The Piccolo® Lipid Panel – Capillary Reagent Disc (which contains the Piccolo® Total Cholesterol – Capillary 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.

5. Statement of Intended Use:

The Piccolo Total Cholesterol – Capillary Test System used with the Piccolo xpress Chemistry Analyzer is intended for the *in vitro* quantitative determination of total cholesterol in capillary (fingerstick) heparinized whole blood in a clinical laboratory setting or point-of-care location.

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

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 – Capillary Test System in comparison to the legally marketed predicate device.

Summary of Safety and Effectiveness (continued)

Table 1: Specification Comparison for Piccolo Total Cholesterol – Capillary Test System and the Roche Total Cholesterol Test on the Cobas 6000 Analyzer

	Piccolo Total Cholesterol – Capillary Test on Abaxis Chemistry Analyzer	**Roche Total Cholesterol Test on the Cobas 6000 Analyzer**
Intended Use	Quantitative analysis of Total Cholesterol	Quantitative analysis of Total Cholesterol
Methodology	Enzymatic endpoint reaction	Enzymatic endpoint reaction
Sample Type	Lithium heparinized capillary whole blood	Lithium and potassium heparinized plasma and serum
Dynamic Range Lower Limit	20 mg/dL	3.86 mg/dL
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid reagent
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	20 - 520 mg/dL	3.86 - 800 mg/dL
Testing Environment	Professional use	Professional use
Sample Size	Approx 100 µL	2 µL

Summary of Safety and Effectiveness (continued)

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 – Capillary Test System. This device is for the addition of capillary sampling on the previously cleared device K023642.

Linearity:

The dynamic range of the Piccolo® Total Cholesterol – Capillary Test System is from 20 to 520 mg/dL. This was established using samples across the measuring range, see previously cleared submission K023642. Testing was done using a total of 20 Piccolo analyzers to ensure that the recoveries were not instrument-specific.

Table 2: Summary of Linearity

	Total Cholesterol – Capillary
Slope	0.989
Intercept	19.7
Correlation Coefficient (r)	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 Abaxis analyzer.

Summary of Safety and Effectiveness (continued)

Table 3: Within-Run and Total Precision of Total Cholesterol Assayed on the Abaxis Analyzer

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

Table 4: Whole Blood Precision for Total Cholesterol Assayed on the Abaxis Analyzer: Five fresh whole blood samples were tested seven times on four analyzers over a period of three hours; a total of 20 analyzers were used.

Total Cholesterol (mg/dL)

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Mean	210.8	216.8	239.1	184.2	236.2
SD	3.6	3.1	3.8	3.2	3.6
%CV	1.7	1.4	1.6	1.7	1.5
n	28	28	28	28	28

Summary of Safety and Effectiveness (continued)

Method Comparison:

Table 5: Method Comparison Data for Total Cholesterol Assayed by the Abaxis Piccolo Total Cholesterol – Capillary Test System and the Roche Cholesterol Test – Site 1

Parameters	Statistics
Piccolo Total Cholesterol – Capillary: Singlicate Values, N	216
Roche Cholesterol Assay: Average of Duplicates, N	216
Piccolo Total Cholesterol – Capillary: Mean	186.5
Roche Cholesterol Assay: Mean	190.6
Piccolo Total Cholesterol – Capillary: Std. Dev.	53.6
Roche Cholesterol Assay: Std. Dev	55.3
Piccolo Total Cholesterol – Capillary: Range of Samples	21 - 283
Roche Cholesterol Assay: Range of Samples (Plasma)	23.5 – 289.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	216	216
Slope (95% CI)	0.97 (0.95 to 0.98)	0.97 (0.96 to 0.98)
Intercept (95% CI)	2.42 (-0.10 to 4.95)	1.57 (-0.63 to 3.78)
Correlation Coefficient (R^2)	0.991	0.991
Std. Error of the Estimate (SEE)	5.2	5.2

Summary of Safety and Effectiveness (continued)

Table 6: Method Comparison Data for Total Cholesterol Assayed by the Abaxis Piccolo Total Cholesterol – Capillary Test System and the Roche Cholesterol Test – Site 2

Parameters	Statistics
Piccolo Total Cholesterol – Capillary: Singlicate Values, N	210
Roche Cholesterol Assay: Average of Duplicates, N	210
Piccolo Total Cholesterol – Capillary: Mean	185.9
Roche Cholesterol Assay: Mean	190.8
Piccolo Total Cholesterol – Capillary: Std. Dev.	56.0
Roche Cholesterol Assay: Std. Dev	58.1
Piccolo Total Cholesterol – Capillary: Range of Samples	21 - 412
Roche Cholesterol Assay: Range of Samples (Plasma)	24 – 442.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	210	210
Slope (95% CI)	0.96 (0.95 to 0.97)	0.96 (0.95 to 0.98)
Intercept (95% CI)	2.83 (0.28 to 5.37)	1.99 (-1.08 to 5.07)
Correlation Coefficient (R^2)	0.991	0.991
Std. Error of the Estimate (SEE)	5.4	5.4

Summary of Safety and Effectiveness (continued)

Table 7: Method Comparison Data for Total Cholesterol Assayed by the Abaxis Piccolo Total Cholesterol – Capillary Test System and the Roche Cholesterol Test – Site 3

Parameters	Statistics
Piccolo Total Cholesterol – Capillary: Singlicate Values, N	213
Roche Cholesterol Assay: Average of Duplicates, N	213
Piccolo Total Cholesterol – Capillary: Mean	184.9
Roche Cholesterol Assay: Mean	190.9
Piccolo Total Cholesterol – Capillary: Std. Dev.	51.2
Roche Cholesterol Assay: Std. Dev	52.9
Piccolo Total Cholesterol – Capillary: Range of Samples	22 - 320
Roche Cholesterol Assay: Range of Samples (Plasma)	23.5 – 340.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	213	213
Slope (95% CI)	0.96 (0.95 to 0.98)	0.97 (0.95 to 0.98)
Intercept (95% CI)	1.30 (-1.73 to 4.33)	0.09 (-2.48 to 2.65)
Correlation Coefficient (R^2)	0.987	0.987
Std. Error of the Estimate (SEE)	6.0	6.0

Summary of Safety and Effectiveness (continued)

Table 8: Method Comparison Data for Total Cholesterol Assayed by the Abaxis Piccolo Total Cholesterol – Capillary Test System and the Roche Cholesterol Test – Combined Data

Parameters	Statistics
Piccolo Total Cholesterol – Capillary: Singlicate Values, N	639
Roche Cholesterol Assay: Average of Duplicates, N	639
Piccolo Total Cholesterol – Capillary: Mean	185.8
Roche Cholesterol Assay: Mean	190.8
Piccolo Total Cholesterol – Capillary: Std. Dev.	53.5
Roche Cholesterol Assay: Std. Dev	55.4
Piccolo Total Cholesterol – Capillary: Range of Samples	21 - 412
Roche Cholesterol Assay: Range of Samples (Plasma)	23.5 – 442.5

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	639	639
Slope (95% CI)	0.96 (0.95 to 0.97)	0.97 (0.96 to 0.98)
Intercept (95% CI)	2.20 (0.64 to 3.76)	1.23 (-0.29 to 2.75)
Correlation Coefficient (R^2)	0.989	0.989
Std. Error of the Estimate (SEE)	5.6	5.6

8. Accuracy

Accuracy of the Piccolo method for Cholesterol was established by completing the certification process of the CRMLN.

9. Conclusions

The clinical and non-clinical tests performed using the Piccolo® Total Cholesterol – Capillary Test System, when run on the Piccolo® xpress Chemistry Analyzer, demonstrate that the test system is as safe, effective and performs as well as the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 15, 2013

Abaxis, Inc.
c/o Dennis M. Bleile, Ph.D.
3240 Whipple Road
Union City, CA 94587

Re: k130200
Trade/Device Name: Piccolo® Total Cholesterol - Capillary Test System
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)
Product Code: CHH
Dated: January 25, 2013
Received: January 28, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K130200

Device Name: Piccolo® Total Cholesterol – Capillary Test System

Indications for Use:

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

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K130200