K120664 APR 2 4 2012

APPENDIX D   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:	March 2, 2012
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® Triglycerides - Capillary Test System

Classification Name: Triglycerides Test system   862.1705

3.   Identification of Legally Marketed Devices to which the Submitter Claims Equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Devices			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Piccolo® Triglycerides Test System	Abaxis Union City, CA	K023639	1/24/2003
Cobas® Triglycerides Test	Roche Diagnostics Indianapolis, IN	K893973	08/11/1989

Summary of Safety and Effectiveness (continued)

4. **Description of the Device:**

    The Piccolo® Lipid Panel – Capillary Reagent Disc (which contains the Piccolo® Triglycerides – 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 Triglycerides – Capillary Test System used with the Piccolo xpress Chemistry Analyzer is intended for the *in vitro* quantitative determination of triglycerides in capillary (fingerstick) heparinized whole blood 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® Triglycerides – Capillary Test System in comparison to the legally marketed predicate device.

Summary of Safety and Effectiveness (continued)

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

	Piccolo Triglycerides – Capillary Test on Abaxis Chemistry Analyzer	Piccolo Triglycerides Test on Abaxis Chemistry Analyzer	Roche Triglycerides Test on the Cobas 6000 Analyzer
Intended Use	Quantitative analysis of Triglycerides	Quantitative analysis of Triglycerides	Quantitative analysis of Triglycerides
Methodology	Enzymatic endpoint reaction	Enzymatic endpoint reaction	Enzymatic endpoint reaction
Sample Type	Lithium heparinized capillary whole blood	Lithium heparinized whole blood, heparinized plasma, and serum	Lithium heparin and potassium EDTA plasma and serum
Dynamic Range Lower Limit	20 mg/dL	20 mg/dL	3.86 mg/dL
Reagents	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Dry test-specific reagent beads and liquid diluent; reconstitution performed by analyzer	Liquid reagent
Temperature of Reaction	37°C	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	20–500 mg/dL	20–500 mg/dL	8.85–885 mg/dL
Testing Environment	Professional use	Professional use	Professional use
Sample Size	Approx 100 µL	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® Triglycerides Test System.

Linearity:

Table 2: Summary of Linearity

	Triglycerides
Slope	1.000
Intercept	3.0
Correlation Coefficient (r)	1.000

Precision:

Precision studies were designed to evaluate within-run and total precision of triglycerides included on the Piccolo® Lipid Panel Reagent Disc when run on the Abaxis analyzer.

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

	Within-Run (n =160)	Total (n =160)
Triglycerides (mg/dL)		
<u>Serum 1</u>		
Mean	206.8	206.8
SD	4.7	5.5
%CV	2.3	2.6
<u>Serum 2</u>		
Mean	163.7	163.7
SD	1.8	2.4
%CV	1.1	1.5

Summary of Safety and Effectiveness (continued)

Method Comparison:

Table 4:   Method Comparison Data for Triglycerides Assayed by the Abaxis Piccolo Triglycerides – Capillary Test System and the Roche Triglycerides Test

Parameters	Statistics
Piccolo Triglycerides – Capillary: Singlicate Values, N	588
Roche Triglycerides Assay: Average of Duplicates, N	588
Piccolo Triglycerides – Capillary: Mean	155.4
Roche Triglycerides Assay: Mean	157.5
Piccolo Triglycerides – Capillary: Std. Dev.	88.3
Roche Triglycerides Assay: Std. Dev	91.6
Piccolo Triglycerides – Capillary: Range of Samples	36 - 496
Roche Triglycerides Assay: Range of Samples	33.5 - 528

Parameters (Roche on X Axis)	Linear Regression	Deming Regression
N	588	588
Slope (95% CI)	0.96 (0.95 to 0.97)	0.96 (0.95 to 0.97)
Intercept (95% CI)	4.1 (2.8 – 5.4)	3.5 (2.1 to 4.9)
Correlation Coefficient (R^2)	0.992	0.992
Std. Error of the Estimate (SEE)	7.9	7.9

8.   Conclusions

The clinical and non-clinical tests performed using the Piccolo® Triglycerides – 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.

10903 New Hampshire Avenue
Silver Spring, MD 20993

Abaxis, Inc.
c/o Dennis M. Bleile, Ph.D., RAC
Director of Assay Performance and Compliance
3240 Whipple Road
Union City, CA 94587

APR 2 4 2012

Re: k120664
Trade/Device Name: Piccolo Triglycerides – Capillary Test System
Regulation Number: 21 CFR 862.1705
Regulation Name: Triglyceride Test System
Regulatory Class: Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(4)
Product Code: JGY
Dated: March 2, 2012
Received: March 5, 2012

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
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): _____

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

Intended Use:

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

Indications for Use:

Triglyceride measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, and other diseases involving lipid metabolism, or various endocrine disorders.
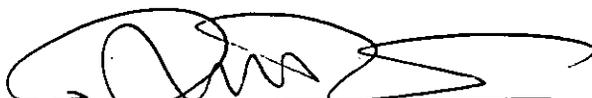
Prescription Use ___**X**___   AND/OR   Over- The Counter Use _____
(Part 21 CFR 801.109 Subpart D)   (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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