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

July 11, 2017

ACON LABORATORIES INC.
QIYI XIE, SR. STAFF CLINICAL/REGULATORY AFFAIRS
10125 MESA RIM ROAD
SAN DIEGO, CA 92121

Re: K163406
Trade/Device Name: Mission Cholesterol Monitoring System
Mission Cholesterol Pro Monitoring System
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: I, meets the limitation to the exemption 21 CFR 862.9(c)(4)
Product Code: CHH, JGY, LBR
Dated: April 10, 2017
Received: April 12, 2017

Dear Dr. Qiyi Xie:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Kellie B. Kelm -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k163406

Device Name
Mission® Cholesterol Monitoring System

Indications for Use *(Describe)*
The Mission® Cholesterol Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary whole blood from the fingertip. The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

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

HDL (High Density Lipoprotein Cholesterol) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Triglycerides 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.

Use this product at the frequency your doctor recommends for testing Total Cholesterol, HDL Cholesterol, and Triglycerides.

An estimated value for Low Density Lipoprotein Cholesterol is calculated by the Mission Cholesterol Meter and is reported only when Triglycerides are $\leq$400 mg/dL.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k163406

Device Name
Mission® Cholesterol Pro Monitoring System

Indications for Use *(Describe)*
The Mission® Cholesterol Pro Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary whole blood from the fingertip and lithium heparin venous whole blood. The Mission Cholesterol Pro Monitoring System is a portable system consisting of the Mission Cholesterol Pro Meter, Mission Cholesterol Pro Test Cartridges, Mission Cholesterol Optical Verifier, and Mission Cholesterol Control Solution, and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.

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

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

Triglycerides 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.

An estimated value for Low Density Lipoprotein Cholesterol is calculated by the Mission Cholesterol Meter and is reported only when Triglycerides are ≤400 mg/dL.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

This summary of 510(k) 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 k163406

Submitter's Identification:

ACON Laboratories, Inc.

10125 Mesa Rim Road

San Diego, California 92121

Tel.: 858-875-8019

Fax: 858-875-8011

Date Prepared: June 27, 2017

Contact Person:

Qiyi Xie

Senior Staff, Clinical & Regulatory Affairs

Email: qxie@aconlabs.com

Proprietary Name of the Device:

Professional use:

Mission® Cholesterol Pro Monitoring System

Mission® Cholesterol Pro Test Cartridge

Home use:

Mission® Cholesterol Monitoring System

Mission® Cholesterol Test Cartridge

Common Name:

Cholesterol (total) Test System, Triglyceride Test System, Lipoprotein Test System

Regulation :

21 CFR 862.1175, 862.1705, 862.1475

Classification:

Class I, meet the limitation of exemption per 21 CFR 862.9(c)(4)

Predicate Device:

Cardiochek Plus and Home Test System
510(k) Number: K140068

Polymer Technology Systems, Inc.
7736 Zionsville Rd
Indianapolis, IN 46268

Device Name:

1) **Mission® Cholesterol Monitoring System (home use)**

Proprietary Name	Regulation - Classification	Product Code	Description
Mission® Cholesterol Monitoring System Mission® Cholesterol Meter Mission® Cholesterol Test Cartridges	21 CFR 862.1175 – Class I	CHH	Cholesterol (total) Test System
	21 CFR 862.1705 – Class I	JGY	Triglyceride Test System
	21 CFR 862.1475 – Class I	LBR	Lipoprotein Test System

2) **Mission® Cholesterol Pro monitoring system (professional use):**

Proprietary Name	Regulation - Classification	Product Code	Description
Mission® Cholesterol Pro Monitoring System Mission® Cholesterol Pro Meter Mission® Cholesterol Pro Test Cartridges	21 CFR 862.1175 – Class I	CHH	Cholesterol (total) Test System
	21 CFR 862.1705 – Class I	JGY	Triglyceride Test System
	21 CFR 862.1475 – Class I	LBR	Lipoprotein Test System

Device Description:

1) **Over the Counter (home use):** The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution and is intended to be used by a single person and should not be shared.
   The Mission Cholesterol Monitoring System is designed for the quantitative measurement of Total Cholesterol (CHOL), High Density Lipoprotein Cholesterol (HDL) and Triglycerides (TRIG) in capillary whole blood from the fingertip. The Mission Cholesterol Meter is an in vitro diagnostic device consisting of a reflectance photometer that analyzes the intensity and color of light reflected from the reagent area of the test cartridge. This device measures analytes in blood once the blood is applied to dry phase test cartridges that are specifically designed for reflectance analysis.

2) **Professional:** The Mission Cholesterol Pro Monitoring System is a portable system consisting of the Mission Cholesterol Pro Meter, Mission Cholesterol Pro Test Cartridges, Mission Cholesterol Pro Optical Verifier and Mission Cholesterol Pro Control Solution and is intended for professional use in healthcare settings for multiple patient uses.
   The Mission Cholesterol Pro Monitoring System is designed for the quantitative measurement of Total Cholesterol (CHOL), High Density Lipoprotein Cholesterol (HDL) and Triglycerides (TRIG) in capillary and venous human whole blood. The Mission Cholesterol Pro Meter is an in vitro diagnostic device consisting of a reflectance photometer that analyzes the intensity and color of light reflected from the reagent area of the test cartridge. This device measures analytes in blood once the blood is applied to dry phase test cartridges that are specifically designed for reflectance analysis.

<u>Test Cartridge:</u>

The Mission Cholesterol (Home use) Test Cartridge is a 3 in 1 Lipid Panel test device used to measure concentration of CHOL, HDL and TRIG in capillary whole blood from the fingertip.
A code Chip automatically calibrates the meter with the code number of the cartridges when inserted into the meter.

The Mission Cholesterol Pro (Professional) Test Cartridge is a 3 in 1 Lipid Panel test device used to measure concentration of CHOL, HDL and TRIG in capillary and venous human whole blood. A code Chip automatically calibrates the meter with the code number of the cartridges when inserted into the meter.

Control Solution:

Both the Mission® Cholesterol (home use) Monitoring System's and the Mission® Cholesterol Pro Monitoring System's Control Solutions are used to estimate precision of meter readings for determination of total cholesterol (CHOL), high density lipoprotein cholesterol (HDL) and triglycerides (TRIG).

Optical verifier:

Both the Mission® Cholesterol (home use) Monitoring System's and the Mission® Cholesterol Pro Monitoring System's Optical Verifiers are used to verify that the meter functions properly by checking that the meter can detect a pre-calibrated value.

Intended Use:

1) Over the Counter Use:

The Mission® Cholesterol Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary whole blood from the fingertip. The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.

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

HDL (High Density Lipoprotein Cholesterol) measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Triglycerides 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.

Use this product at the frequency your doctor recommends for testing Total Cholesterol, HDL Cholesterol and Triglycerides.

An estimated value for Low Density Lipoprotein Cholesterol is calculated by the Mission Cholesterol Meter and is reported only when Triglycerides are ≤400 mg/dL.

2) Professional Use:

The Mission® Cholesterol Pro Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary whole blood from the fingertip and lithium heparin venous whole blood. The Mission® Cholesterol Pro Monitoring System is a portable system consisting of the Mission Cholesterol Pro Meter, Mission Cholesterol Pro Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto- disabling lancing devices. This system is for in vitro diagnostic use only.

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

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

Triglycerides 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.

An estimated value for Low Density Lipoprotein Cholesterol is calculated by the Mission Cholesterol Meter and is reported only when Triglycerides are ≤400 mg/dL.

Technological Characteristics:

Specification of the Mission® Cholesterol Monitoring (Home use) and Mission® Cholesterol Pro Monitoring Meters:

Feature	Specifications
Methodology	Reflectance Photometer
Test Time	≤ 2 min
Measurement Range	CHO: 100-400mg/dL (2.59-10.36 mmol/L,1mmol/l=38.66mg/dL) HDL: 15-100 mg/dL (0.39-2.59 mmol/L, 1mmol/l=38.66mg/dL) TRIG: 45-650 mg/dL (0.51-7.34 mmol/L, 1mmol/l=38.6mg/dL)
Specimen	Whole blood
Specimen Volume	35 μL
Power Source	4 AAA batteries (1.5V)
	AC Adapter (Mini USB, 5V dc, 50 mA)
Battery Life	85 hours or 1,000 tests
Units of Measurement	mg/dL
Memory	200 records
Automatic Shut Off	5 minutes after last use
Meter Size	137 mm × 79 mm × 26 mm (5.4" × 3.11" ×1.02")
Display Size	50 mm × 50 mm (1.97" ×1.97")
Weight	145g (without batteries)
Meter Storage Conditions	0 - 50ºC (32 -122ºF); ≤ 90% RH
Operating Conditions	15 - 40ºC (59 -104ºF); 20- 90% RH
Meter Connectors	USB cable for Printer or Power (optional)

Special conditions for use statement(s):

Over-the-counter:

- Do not test samples other than fresh capillary whole blood obtained from the fingertip.
- For single-patient use only.
- Do not use on neonates.
- Do not reuse; each Test Cartridge is for single use only.

- Users with low or high red blood cell counts (e.g. users with anemia or polycythemia) may have inaccurate results.
- Do not use when Hematocrit is outside the acceptable Hematocrit range for testing of 30% to 50%.
- Users with dehydration or peripheral vascular disease should avoid fingertip testing.
- Do not use when humidity is higher than 90% and lower than 20%, as extremes in humidity may affect results.
- Critically ill patients should not use this test.
- Do not use test cartridge after the expiration date shown on the pouch.
- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.
- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.

Prescription use:

- Do not use on neonates.
- Do not reuse; each Test Cartridge is for single use only.
- Users with low or high red blood cell counts (e.g. users with anemia or polycythemia) may have inaccurate results.
- Do not use when Hematocrit is outside the acceptable Hematocrit range for testing of 30% to 50%.
- Users with dehydration or peripheral vascular disease should avoid fingertip testing.
- Do not use when humidity is higher than 90% and lower than 20%, as extremes in humidity may affect results.
- Critically ill patients should not use this test.
- Do not use test cartridge after the expiration date shown on the pouch.
- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.
- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.
- Heparin is recommended anticoagulant for use with venous whole blood. Do not use other anticoagulants, e.g. iodoacetate, sodium citrate or those containing fluoride. Arterial blood is not recommended for use. Hemolyzed blood or thrombolytic therapy blood may lower the results. Venous occlusion might increase the results and is not recommended for blood draws.

Special instrument requirements:

Mission Cholesterol Meter and Mission Cholesterol Pro Meter

Substantial Equivalence:

Predicate device name:

CardioChek Plus Test System and CardioChek Home Test System – K140068

Comparison with predicate:

1. **Home Use**

Features	Mission® Cholesterol Monitoring System	CardioChek Home Test System (K140068)
Comparison		
Indications for Use	The Mission® Cholesterol Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary whole blood from the fingertip. The Mission Cholesterol Monitoring System is a portable system consisting of the Mission Cholesterol Meter, Mission Cholesterol Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only.	The CardioChek Home Test System is a small portable analyzer and test strip system for self-testing by lay users. It is intended to be used by a single person and should not be shared. This system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in capillary whole blood from the fingertip. *A* Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.
Intended Use/ Setting	The Mission® Cholesterol Monitoring System is intended for single person use, not to be shared.	Same as CardioChek Home Test System
Methodology	Reflectance Photometer	Same
Test Time	≤ 2 min	≤ 90 seconds
Measurement Range	CHOL: 100-400mg/dL (2.59-10.36 mmol/L) HDL: 15-100 mg/dL (0.39-2.59 mmol/L) TRIG: 45-650 mg/dL (0.51-7.34 mmol/L)	CHOL: 100-400mg/dL (2.59-10.36 mmol/L) HDL: 15-100 mg/dL (0.39-2.59 mmol/L) TRIG: 50-500 mg/dL (0.57-5.65 mmol/L)
Specimen	Capillary Whole Blood	Same
Calibration Coding	Automatic calibration by the code chip	Same

Sample Volume	35 µL (25-50 µL)	15 to 40 µL
Units of Measurement	mg/dL (default), mmol/L	Same
Operating Conditions	15 - 40ºC (59 -104ºF); 20-90% RH	10-40°C (50-104°F), Between 20 and 80% RH
Storage Conditions	0 - 50ºC (32 -122ºF); ≤ 90% RH	Same
Hematocrit Range	CHOL, HDL, TRIG: 30-50%	CHOL: 30~50% HDL: 30~45% TG: 15~55%
Meter Connectors	USB cable for Printer or Power (optional)	Same
Power Source	4 AAA batteries (1.5V) AC Adapter (Mini USB, 5V dc, 50 mA)	4 AA batteries (1.5V)
Meter Size	Width: 3.11" (7.89 cm) Length: 5.4" (13.7 cm) Height: 1.02" (2.6 cm)	Width: 3.2 in (8.13 cm) Length: 6.0 in (15.24 cm) Height: 1.5 in (3.8 cm)
Meter Weight	145g (without batteries)	156g (without batteries)
Battery Life	85 hours or 1,000 tests	300 tests

2. Professional Use

Features	**Mission® Cholesterol Pro Monitoring System**	**CardioChek Plus Test System (K140068)**
Comparison		
Indications for Use	The Mission® Cholesterol Pro Monitoring System is intended for the quantitative determination of Total Cholesterol, High Density Lipoprotein Cholesterol, and Triglycerides in human capillary	The CardioChek Plus Test System is a small portable analyzer and test strip system intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto disabling lancing devices. This

	whole blood from fingertip and lithium heparin venous whole blood. The Mission® Cholesterol Pro Monitoring System is a portable system consisting of the Mission Cholesterol Pro Meter, Mission Cholesterol Pro Test Cartridges, Mission Cholesterol Optical Verifier and Mission Cholesterol Control Solution, and is intended for multiple patient use in professional healthcare settings. This system should only be used with single-use, auto-disabling lancing devices. This system is for in vitro diagnostic use only.	system is for in vitro diagnostic use only. The tests strips are for the quantitative determination of glucose, total cholesterol, HDL (high density lipoprotein) cholesterol and triglycerides in venous whole blood and capillary whole blood from the fingertip. A Chol/HDL ratio and estimated values for LDL (low density lipoprotein) cholesterol and non-HDL cholesterol are calculated by the CardioChek Plus analyzer.
Specimen	Capillary and venous whole blood	Same
Storage	• Store as packaged in the sealed pouch, either at room temperature or refrigerated. • Temperature: 36-86ºF, 2-30°C • Do not freeze. • Keep out of direct sunlight	Same
Shelf life	Test cartridges are stable through the expiration date printed on the test cartridge foil pouch.	Same
Enzyme	CHOL: Cholesterol esterase, Cholesterol oxidase, 4-aminoantipyrine HDL: Dextran sulphate, cholesterol esterase, cholesterol oxidase, 4-aminoantipyrine TRIG: Lipoprotein lipase, glycerol kinase, glycerol phosphate oxidase, 4-aminoantipyrine	CHOL: Cholesterol esterase, Cholesterol oxidase, Peroxidase HDL: Cholesterol esterase, Cholesterol oxidase, Peroxidase TRIG: Lipase lipoprotein, Glycerol kinase, Glycerol-3-Phosphate Oxidase, Peroxidase
Measurement Range	CHOL: 100-400mg/dL (2.59-10.36 mmol/L) HDL: 15-100 mg/dL (0.39-2.59 mmol/L) TRIG: 45-650 mg/dL (0.51-7.34 mmol/L)	CHOL: 100-400mg/dL (2.59-10.36 mmol/L) HDL: 15-100 mg/dL (0.39-2.59 mmol/L) TRIG: 50-500 mg/dL (0.57-5.65 mmol/L)
Meter Connectors	USB cable for Printer or Power (optional)	Same

Power Source	4 AAA batteries (1.5V) AC Adapter (Mini USB, 5V dc, 50 mA)	4 AA batteries (1.5V)
Meter Size	Width: 3.11" (7.89 cm) Length: 5.4" (13.7 cm) Height: 1.02" (2.6 cm)	Width: 3.2 in (8.13 cm) Length: 6.0 in (15.24 cm) Height: 1.5 in (3.8 cm)
Meter Weight	145g (without batteries)	156g (without batteries)
Battery Life	85 hours or 1,000 tests	300 tests

Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Laboratory Performance Testing:

The performance characteristics of the Mission Cholesterol Monitoring System were verified by Precision study, Interference study, Temperature flex study, Humidity flex study, Sample volume flex , sensitivity study, hematocrit effect study, temperature effect study, stability study, meter performance validation, electrical safety testing and EMC testing. Laboratory testing results indicate that the Mission Cholesterol Monitoring System is robust and can perform satisfactorily when used with the test cartridges and control solution according to the "Indication for Use" statement specified in the Instruction Manual and Package Insert of the device.

a. Precision

Precision was determined according to the CLSI Guideline EP05-A3. The precision study was performed at three point-of-care (POC) sites using three lots of Mission® Cholesterol (and Pro) Test Cartridges. Precision studies were performed with whole blood samples and control solutions. To estimate different sources of variance, the data set was fitted to a Mixed Effects Model using the commercial software package lme4 (version: 1.1-12) in R (version 3.3.1).

For laboratory workers testing precision with control solutions at three clinical sites, the following results were obtained:

	%CV					
	Total Cholesterol		High Density Lipoprotein		Triglycerides	
	Level 1	Level 2	Level 1	Level 2	Level 1	Level 2
Repeatability	1.5%	1.6%	2.0%	1.6%	1.3%	1.6%
Total precision	2.0%	1.8%	2.7%	2.3%	2.0%	1.9%

b. Linearity/ assay reportable range:

A linearity study was performed according to NCCLS EP6-A at 9 concentration levels for each parameter and tested using 10 replicates each over three lots of the mission cholesterol test cartridges. This study demonstrates that the Mission® Cholesterol Test System is linear over the following reportable ranges:

The measurement range of total cholesterol (100-400 mg/dL) is within the linear detection range.
The measurement range of HDL (15-100 mg/dL) is within the linear detection range.
The measurement range of triglyceride (45-650 mg/dL) is within the linear detection range.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

ACON Labs has documented traceability to the NCEP's recommended accuracy base for Total Cholesterol and HDL by performing a direct comparison with a Cholesterol Reference Method Laboratory Network (CRMLN) laboratory using fresh human specimens which cover the NCEP medical decision points. Triglyceride test is traceable to NIST standard.

No calibration is required to perform the cholesterol test; however a lot specific code chip is provided with each test cartridge. The user must check and make sure that the code number printed on the test cartridge vial matches the code number displayed on the cholesterol meter before testing.

Stability:

Accelerated time stability studies were conducted to assess the shelf-life of test cartridges and it is estimated to be 18 months.

Detection limit:

Limit of blank, limit of detection and limit of quantitation studies were performed and support the following reportable measuring ranges:

CHOL: 100-400mg/dL

HDL: 15-100 mg/dL

TRIG: 45-650 mg/dL

d. Analytical specificity:

Studies were performed according to CLSI guideline EP7-A2 to determine whether endogenous and exogenous substances interfere with the Mission Cholesterol Monitoring System's Cholesterol. HDL and Triglyceride assays. No Interference was observed for the following substances at the concentrations in the table below for total cholesterol (CHOL), HDL and Triglyceride (TG):

1. Interference from Endogenous Substances			
Endogenous Substance	Concentration showing no interference		
	CHOL	HDL	TRIG
Bilirubin	15 mg/dL	15 mg/dL	33.2 mg/dL
Creatinine	5 mg/dL	5 mg/dL	5 mg/dL
Hemoglobin	500 mg/dL	500 mg/dL	500 mg/dL
Uric acid	12 mg/dL	12 mg/dL	23.5 mg/dL
Cholesterol	/	/	502 mg/dL
Triglyceride	649 mg/L	649 mg/L	/
2. Interference from Exogenous Substances			
Exogenous Substance	Concentration showing no interference		
	CHOL	HDL	TRIG
Acetylsalicylic acid	65 mg/dL	65 mg/dL	65 mg/dL
Acetaminophen	20 mg/dL	20 mg/dL	20 mg/dL
Atorvastatin	0.06 mg/dL	0.06 mg/dL	0.06 mg/dL
Ampicillin	5.3 mg/dL	5.3 mg/dL	5.3 mg/dL
Ascorbic acid	10 mg/dL	10 mg/dL	10 mg/dL
Bezafibrate	10 mg/dL	10 mg/dL	10 mg/dL
Dopamine	0.09 mg/dL	0.09 mg/dL	0.09 mg/dL
Furosemide	6 mg/dL	6 mg/dL	6 mg/dL
Gentisic acid	1.8 mg/dL	1.8 mg/dL	1.8 mg/dL
Glybenclamide	1 mg/dL	1 mg/dL	1 mg/dL

Ibuprofen	50 mg/dL	50 mg/dL	50 mg/dL
Indomethacin	3.6 mg/dL	3.6 mg/dL	3.6 mg/dL
Methyldopa	1.5 mg/dL	1.5 mg/dL	1.5 mg/dL
Nicotinic acid	0.1 mg/dL	0.1 mg/dL	0.1 mg/dL
Probenecid	60 mg/dL	60 mg/dL	60 mg/dL
Quinidine hydrochloride monohydrate	1.2 mg/dL	1.2 mg/dL	1.2 mg/dL
Salicylic acid	60 mg/dL	60 mg/dL	60 mg/dL
Sulfamethoxazole	40 mg/dL	40 mg/dL	40 mg/dL
Trimethoprim	4 mg/dL	4 mg/dL	4 mg/dL

Limitations:

- High concentrations of uric acid (≥12 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.
- High concentrations of bilirubin (≥15 mg/dL) can lead to falsely low measurements for Total Cholesterol and HDL Cholesterol.

Discussion of Clinical Tests Performed:

The clinical study followed the FDA's "Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use." A total of 369 patients were recruited for the study at three POL sites located in different geographical locations.
The study design incorporated testing for both professional use and self-testing.

For professional use, patient blood was collected from fingertip and venous blood draws. Capillary blood samples from fingertip were tested at clinical sites by professionals. Venous blood samples were tested at a laboratory using an FDA cleared method.
For self-testing, laypersons followed the product package insert and performed the test with their capillary finger blood from fingers using Mission® Cholesterol Monitoring System and test cartridge.

Finger blood and venous blood specimens were collected from 369 laypersons at three clinical sites and were tested with Mission® Cholesterol Test Cartridges by medical professionals and laypersons. The plasma concentration was confirmed by the reference method. The tables below show the regression correlation values:

Total cholesterol

Operator	Specimen	Linearity	R^2	No. of Specimens
Layperson	Finger capillary	Y=0.9994X+0.0293	0.9846	369
Professional Operator	Finger capillary	Y=1.0016X-0.5139	0.9883	369
Professional Operator	Heparin Venous	Y=0.9889X+0.807	0.9863	369

HDL cholesterol

Operator	Specimen	Linearity	R^2	No. of Specimens
Layperson	Finger capillary	Y=0.99X+0.0989	0.9768	369
Professional Operator	Finger capillary	Y=1.0015X-0.1705	0.9778	369
Professional Operator	Heparin Venous	Y=0.9929X+1.052	0.9790	369

Triglycerides

Operator	Specimen	Linearity	R^2	No. of Specimens
Layperson	Finger capillary	Y=0.9983X+0.8927	0.9934	369
Professional Operator	Finger capillary	Y=0.9965X+0.9441	0.9948	369
Professional Operator	Heparin Venous	Y=0.9901X-1.2099	0.9936	369

% Bias of Mission Cholesterol Monitoring System at Medical Decision Points

Total Cholesterol		
Specimen	200 mg/dL	240 mg/dL
Finger Blood	-0.1%	-0.1%
Venous Blood	-0.7%	-0.8%

HDL		
Specimen	40 mg/dL	60 mg/dL
Finger Blood	-0.3%	-0.1%
Venous Blood	1.9%	1.0%

Triglyceride			
Specimen	150 mg/dL	200 mg/dL	500 mg/dL
Finger Blood	0.3%	0.0 %	-0.2%
Venous Blood	-1.8%	-1.5%	-1.2%

Conclusion:

The laboratory performance testing and clinical study results demonstrate that the Mission Cholesterol and Mission Cholesterol Pro Monitoring System and Test Cartridges are safe, effective and easy-to-use and as such is substantially equivalent to the predicate devices currently sold on the U.S. market.