510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k132031

B. Purpose for Submission:

New submission

C. Measurand:

Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol, Triglyceride

D. Type of Test:

Quantitative, enzymatic assays

E. Applicant:

Axis-Shield PoC AS

F. Proprietary and Established Names:

Afinion™ Lipid Panel
Afinion™ Lipid Panel Control

G. Regulatory Information:

Product Code	Classification	Regulation	Panel
CHH- Enzymatic Esterase- Oxidase, Cholesterol	Class I*	21 CFR 862.1175 Cholesterol (total) test system	75 Clinical Chemistry (CH)
LBR- LDL & VLDR Precipitation, HDL Cholesterol	Class I*	21 CFR 862.1475 Lipoprotein test system	75 Clinical Chemistry (CH)
JGY- Colorimetric Method, Triglycerides	Class I*	21 CFR 862.1705 Triglyceride test system	75 Clinical Chemistry (CH)
JJY- Multi-Analyte Controls	Class I, reserved	21 CFR 862.1660, Quality Control Material (assayed)	75 Clinical Chemistry (CH)

*Meets limitations of the exemption as per 21 CFR 862.9(c)(4) and 862.9(c)(9)

H. Intended Use:

1. Intended use(s):

   See indications for use (below).

2. Indication(s) for use:

   The Afinion™ Lipid Panel is an in vitro diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

   Afinion™ Lipid Panel Control has been designed for use with the Afinion™ AS100 Analyzer and Afinion™ Lipid Panel. Afinion™ Lipid Panel Control is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig). The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

   For use in clinical laboratories and point of care laboratory settings.

3. Special conditions for use statement(s):

   Prescription use only.

4. Special instrument requirements:

   Afinion™ AS100 Analyzer System (cleared under k050574)

I. Device Description:

Afinion™ Lipid Panel is a fully automated assay for quantitative determination of lipids in serum. The system consists of the Afinion™ AS100 Analyzer and a cartridge for the measurement of Cholesterol, HDL and Triglyceride. (Please note that the Afinion system is not able to measure the HDL level in a sample when the triglyceride level is > 650 mg/dL.) LDL, non- HDL and Chol/HDL are calculated by the analyzer.

The Afinion™ Lipid Panel Test Cartridge contains all reagents necessary for determination of cholesterol, HDL and triglyceride concentrations. The operator fills the sampling device (which is integrated in the test cartridge) with either the patient sample or quality control material. The test cartridge is then placed in the Afinion™ AS100 Analyzer. All testing is performed automatically by the analyzer. Results of the measured or calculated indices are printed by the analyzer.

Additionally, the following indices are calculated:

LDL cholesterol

LDL is calculated according to the Friedwald formula*:

LDL (mg/dL) = Chol – HDL – Trig/5

**This equation is not valid for non-fasting specimen, or in patients with type III hyperlipoproteinemia. No LDL result is provided by the analyzer when triglyceride levels are above 400 mg/dL as the Friedwald formula is less accurate at these triglyceride concentrations*.

non-HDL cholesterol

The sum of VLDL (very low density lipoprotein) + LDL is called non-HDL cholesterol.

Non-HDL cholesterol= total cholesterol- HDL cholesterol.

Chol/HDL ratio

Chol/HDL calculated ratio = Total Cholesterol/ HDL Cholesterol

The **Afinion™ Lipid Panel Controls*** are serum-based assayed materials. The two levels of control are ready to use and are sold separately.

**Each serum/plasma donor unit used in the manufacture of the control products has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag*

Materials required but not provided with the kit

- Afinion™ AS100 Analyzer
- Afinion™ Lipid Panel Control

J. Substantial Equivalence Information:

1. Predicate device names:

   Total Cholesterol: Roche Diagnostics Corp., COBAS INTEGRA CHOLESTEROL GEN.2

   Triglycerides: Roche Diagnostics Corp., ROCHE COBAS INTEGRA REAGENT CASSETTES

   HDL Cholesterol: Siemens ADVIA 2400 Direct HDL Cholesterol

   Quality Control: Clinica Corp, CLINIQA Liquid QC Lipid Controls Levels 1 and 2

2. Predicate 510(k) number(s):

   k031824, k972250, k982341, and k061182, respectively.

3. Comparison with predicate:

Characteristic	Roche Diagnostics Corp. Cholesterol (Predicate)	Afinion™ Lipid Panel Total Cholesterol
Intended Use	Same	*In vitro* diagnostic test for quantitative determination of total cholesterol (Chol).
Test principle	Same	Enzymatic colorimetric test.
Specimen type	Serum Plasma	Serum
Reporting range	3.86-800 mg/dL	100-500 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	10 minutes Batch testing	8 minutes Single tests
Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (Hitachi)	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottle of Reagent 1	Ready to use test cartridges
Reagents and controls storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C

Characteristic	**Roche Diagnostics Corp.** **Triglycerides** **(Predicate)**	**Afinion™ Lipid Panel** **Analyte: Triglycerides (Trig)**
Intended Use	Same	*In vitro* diagnostic test for quantitative determination of triglycerides (Trig).
Test principle	Same	Enzymatic colorimetric test.
Specimen type	Serum Plasma	Serum
Reporting range	8.85-885 mg/dL	45-650 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the test cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	5 minutes Batch testing	8 minutes Single tests
Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (Hitachi)	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottle of Reagent 1	Ready to use test cartridges

Reagents and controls storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C
Characteristic	**Siemens ADVIA 2400** **HDL-Cholesterol** **(Predicate)**	**Afinion™ Lipid Panel** **Analyte: HDL Cholesterol**
Intended Use	Same	*In vitro* diagnostic test for quantitative determination of high-density lipoprotein (HDL) cholesterol.
Test principle	Enzymatic colorimetric test. Direct determination of HDL-cholesterol. Cholesterol from non-HDL particles is eliminated in the first reaction step. I second step cholesterol in HDL particles is released by detergent and measured by a Trinder reaction.	Enzymatic colorimetric test. Direct determination of HDL by initial antibody blocking of apolipoprotein B (apo-B) , which is present on all lipoproteins except HDL cholesterol.
Specimen type	Serum Plasma	Serum
Reporting range	5-115 mg/dL	15-100 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	10 minutes Batch testing	8 minutes Single tests

Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (ADVIA)	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottles of Reagent 1 and Reagent 2	Ready to use test cartridges
Storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C

Characteristic	**Cliniqa Liquid QC Lipid Control (Predicate)**	**Afinion™ Lipid Panel Control**
Intended Use	Same	Intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig).
Matrix	Same	Human serum
Analyte	Apolipoprotein A-1, Apolipoprotein B, Cholesterol (Total), High Density Lipoprotein, Low Density Lipoprotein and Triglycerides	Total Cholesterol HDL Cholesterol Triglycerides
Form	Liquid – ready to use	Liquid – ready to use
Levels	2	2
Storage conditions	2-8°C	2-8°C
Analytes	Target values also available for Apolipoprotein A1 and Apolipoprotein B and LDL Cholesterol.	No target values for Apolipoprotein A1 and Apolipoprotein B as they are not measured by Afinion™ Lipid Panel. LDL cholesterol is calculated by Afinion™ AS100 Analyzer, and no

		target value for LDL is assigned.
Target value assignment	Target values are method dependent, and assigned values are available for a large number of methods/systems.	Target values are assigned for Afinion™ Lipid Panel.

K. Standard/Guidance Document referenced (if applicable):

1. CLSI EP09-A2-IR Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline- 2nd Edition Interim Rev
2. CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline- 2nd Edition
3. CLSI EP-17-A Protocols for Determination of Limits of Detection and Limits of Quantitation
4. CLSI EP-6 Evaluation of the Linearity of Quantitative Measurement Procedures: Approved Guideline- First Edition
5. ISO 14971:2007, Medical devices - Application of risk management to medical devices
6. CLSI EP7-A2 Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition

L. Test Principle:

Total Cholesterol
Total Cholesterol is measured by an enzymatic colorimetric method. Esterified and free cholesterol are enzymatically converted into cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide is used by hydrogen peroxidase to couple a phenol and 4-aminoantipyrin to a red quinoneimine dye. The color intensity is directly proportional to the concentration of free and esterified cholesterol in the sample.

Triglycerides
Triglycerides are measured by an enzymatic colorimetric method. Triglycerides are enzymatically converted into glycerol by lipoprotein lipase. Glycerol is then further catalyzed in 2 steps to di-hydroxy-acetone-phosphate and hydrogen peroxide. The hydrogen peroxide then reacts with 4-aminophenazone and 4-chlorophenol under the action of peroxidase to form a red dyestuff. The color intensity is directly proportional to the concentration of triglycerides.

HDL Cholesterol
In a first reaction, anti-human apolipoprotein B (apoB) antibody (R1) binds to apoB present on all lipoproteins but HDL (i.e. non-HDL). The antibody protects non-HDL from being degraded by pegylated cholesterol metabolizing enzymes in the second reaction (R2). In the R2 reaction free and esterified cholesterol of HDL are converted into cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide is used by peroxidase to couple 4-aminoantipyrin to F-DAOS and forms a blue color complex. The color intensity is directly proportional to the concentration of free and esterified HDL cholesterol.

M. Performance Characteristics (if/when applicable):

1. Analyticalperformance:

a. Precision/Reproducibility:

Repeatability and Within-device (total) precision was determined according to the CLSI Guideline EP5-A2. The precision study was performed at three point-of-care (POC) sites using one lot of Afinion™ Lipid Panel test cartridges and 2-3 analyzers per site.

Two controls and one serum sample were tested over 20 days with a total of 80 replicates at each site. Two replicates of each level were run two times a day. The results are summarized in the tables below. The estimates of repeatability and Within-device precision are presented below. In the tables: N=number of replicates; SD=Standard deviation, and; CV=Coefficient of Variation.

Cholesterol Repeatability and Within-device Precision (total)

				Repeatability		**Within-device**	
	Site	**N**	**Mean (mg/dL)**	**SD (mg/dL)**	**CV (%)**	**SD (mg/dL)**	**CV (%)**
Control sample	1	80	185.8	3.2	1.7	4.3	2.3
	2	80	186.5	5.5	2.9	6.7	3.6
	3	80	186.3	5.8	3.1	5.6	3.0
Control sample	1	80	249.2	6.3	2.5	6.1	2.4
	2	80	252.4	6.2	2.4	9.8	3.9
	3	80	249.3	8.9	3.5	8.5	3.4
Serum sample	1	80	400.0	7.0	1.7	9.4	2.3
	2	80	401.4	10.2	2.5	12.4	3.1
	3	80	401.4	9.6	2.4	11.1	2.8

HDL Repeatability and Within-device Precision (total)

	Site	N	Mean (mg/dL)	Repeatability		Within-device	
				SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Control sample	1	80	39.8	1.1	2.7	1.3	3.2
	2	80	40.6	1.6	3.9	2.0	4.9
	3	80	40.1	1.1	2.8	1.2	3.1
Control sample	1	80	57.1	1.4	2.5	1.6	2.8
	2	80	59.4	2.1	3.5	2.6	4.4
	3	80	57.9	2.1	3.6	2.1	3.6
Serum sample	1	80	70.8	1.8	2.5	1.8	2.6
	2	80	72.8	1.6	2.2	3.0	4.1
	3	80	72.0	1.5	2.1	1.9	2.6

Triglyceride Repeatability and Within-device Precision (total)

	Site	N	Mean (mg/dL)	Repeatability		Within-device	
				SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Control sample	1	80	153.8	3.6	2.3	4.1	2.7
	2	80	154.5	3.9	2.5	5.4	3.5
	3	80	154.8	4.2	2.7	4.5	2.9
Control sample	1	80	276.2	7.1	2.6	7.1	2.6
	2	80	279.1	5.8	2.1	10.4	3.7
	3	80	276.0	12.2	4.4	13.4	4.9
Serum sample	1	80	343.5	6.3	1.8	7.4	2.2
	2	80	344.1	10.6	3.1	13.5	3.9
	3	80	343.3	9.3	2.7	12.3	3.6

b. Linearity/assay reportable range:

A linearity study was performed according to NCCLS EP6-A by measuring a dilution series of serum samples of each measurand. One low concentration and one high concentration sample was intermixed to produce 11 concentration levels for each measurand. Each level was measured in 4-6 replicates.

Cholesterol:	y=1.000x – 4.5 mg/dL, r2=0.995
Triglycerides:	y=1.009x – 2.9 mg/dL, r2=0.999
HDL Cholesterol:	y=0.991x – 2.4 mg/dL, r2=0.994

Linearity was demonstrated over the following ranges:

Cholesterol:	77-511 mg/dL (Reportable range 100-500 mg/dL)
Triglycerides:	36-691 mg/dL (Reportable range 45-650 mg/dL)
HDL Cholesterol:	14-111 mg/dL (Reportable range 15-100 mg/dL)

The linearity studies support the reportable ranges claimed by the sponsor: Cholesterol: 100 to 500 mg/dL; Triglyceride: 45 to 650 mg/dL and HDL: 15 to 100 mg/dL

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

Traceability

The cholesterol and HDL assays are traceable to the National Reference System for Cholesterol (NRS/CHOL). The triglyceride assay is traceable to a Centers for Disease Control and Prevention (CDC) reference method.

Afinion™ Lipid Panel is CRMLN certified for Total Cholesterol and HDL.

Target value assignment and traceability of Afinion™ Lipid Panel Control

The Afinion™ Lipid Panel is used for target value assignment of the Afinion™ Lipid Panel Control C I and C II. The target values and the corresponding acceptable ranges are derived from replicate analyses (n=18) and are specific for each lot of product. Testing is performed on one operating day using 3 or 6 analyzers. The tests are performed by Axis-Shield using Afinion™ Lipid Panel test cartridges and a representative sampling of the control lot.

Cholesterol and HDL values assigned to the controls are traceable to the National Reference System for Cholesterol (NRS/CHOL). The triglyceride values assigned to the controls are traceable to the Centers for Disease Control and Prevention (CDC) triglyceride reference method.

Estimated target values for Afinion™ Lipid Panel Control

Analyte	Target value range (mg/dL)	
	Control CI	**Control CII**
Total cholesterol	165-210	230-280
HDL cholesterol	34-46	52-70
Triglycerides	130-170	250-305

Afinion™ Lipid Panel Control Stability

Real time stability studies to establish unopened vial stability are ongoing. Afinion™ Lipid Panel Control CI and CII are being measured with the Afinion™ Lipid Panel assay. The Afinion™ Lipid Panel Controls are continuously stored at 2-8 °C and are tested monthly for 12 months. All results are compared to the initial baseline results.

Afinion™ Lipid Panel Control CI and CII were subjected to an opened vial stability study. Control vials were stored at 2-8 °C in the periods between the test points. Testing was performed after 7, 14 and 30 days, and thereafter weekly up to 8 weeks. In between these testing points the vials were opened and samples withdrawn twice a week.

The acceptance criteria for these studies was reviewed and found acceptable. Results from the studies support the following conclusions:

Shelf life: 12 months when stored refrigerated (2-8 °C).
Opened vial stability: 8 weeks when stored refrigerated (2–8°C).

d. Detection limit:

The sponsor performed a detection limit study for the Afinion Lipid Panel according to CLSI guidance document EP17-A.

Five samples with concentration of each measurand near 0 mg/dL were measured in 60 replicates using 3 analyzers and 2 test cartridge lots to determine the LoB. Five low concentration samples were similarly measured in 60 replicates to determine the LoD, i.e., the limits of detection were calculated using the determined LoB value and pooled SD values from the measured LoD samples. Limits of quantitation (LoQ) were based on a determination of limits of the blank (LoB) and Limits of Detection (LoD), i.e., the inter-assay precision of the replicates of low concentration samples

The following limits of quantitation were established, with each value being significantly lower than the lowest reportable value by the analyzer:

Measurand	Total Cholesterol	HDL Cholesterol	Triglycerides
LoQ (mg/dL)	13	1.3	5.9

The reportable measuring ranges claimed by the sponsor are Cholesterol: 100 to 500 mg/dL; Triglyceride: 45 to 650 mg/dL and HDL: 15 to 100 mg/dL.

e. Analytical specificity:

Studies were performed according to CLSI guideline EP7-A2 to determine whether 28 substances interfered with the Afinion™ Cholesterol, HDL and Triglyceride assays. Two levels at medical decision concentrations of each lipid were evaluated. No significant interference (defined as <10%) was observed up to the following concentrations:

- Acetaminophen 200 mg/L
- Acetylsalicylic acid 1000 mg/L
- Acetylcysteine 1590 mg/L
- Ampicillin 1000 mg/L
- Ascorbic acid 6 mg/dL
- Atorvastatin 600 µg/L
- Bilirubin (conjugated and unconjugated) 20 mg/dL
- Calcium dobesilate 0.7 mg/dL
- Cefoxitin 2500 mg/L
- Cyclosporine A 5mg/L
- Cyclosporine C 5mg/L
- Fluvastatin 2.97 mg/L
- Hemoglobin (hemolysis) 500 mg/dL
- Heparin 3000 U/L
- Ibuprofen 500 mg/L
- Intralipid 1000 mg/dL
- Levodopa 15 mg/L
- Lovastatin 216 µg/L
- Metformin 40 mg/L
- Methyldopa 1.4 mg/dL

- Metronidazole 200 mg/L
- Pravastatin 7.32 mg/L
- Rifampicin 64.3 mg/L
- Simvastatin 80.4 µg/L
- Theophylline 100 mg/L
- Tetracycline 50 mg/L

Limitations:

- Calcium dobesilate interferes with Afinion™ Lipid Panel at therapeutic levels and results in falsely low results for all three assays.
- Methyldopa concentrations above 1.4 mg/dL may give falsely low Triglyceride results. This is above toxic levels of Methyldopa and there is no interference at therapeutic levels.
- Acetylcysteine concentrations above 1590 mg/L may give falsely low Triglyceride results.
- Levodopa concentrations above 15 mg/L may give falsely low HDL and Triglyceride results.

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed for each measurand at four point-of-care sites according to CLSI guideline EP09-A2-IR. Single replicates of the Afinion™ Lipid Panel measurements were taken. The number of samples was evenly distributed among the POC sites. Pooled Afinion™ Lipid Panel results from all sites were compared by plotting Afinion results on the Y-axis and automated laboratory method results on the x-axis and performing a regression analysis. Results of the analyses are presented in the tables below. The bias at medical decision points and at elevated concentrations of each measurand was also calculated and is presented in the last table.

Weighted Deming Regression Results of Afinion™ Total Cholesterol Serum Results Compared to Roche Total Cholesterol Serum Results (pooled and per site)

	All	**Site 1**	**Site 2**	**Site 3**	**Site 4**
N	348	83	91	88	86
Intercept (mg/dL)	-4.5	0.0	-6.1	-7.2	-3.8
Slope	1.04	1.02	1.04	1.04	1.04
Correlation coefficient (r)	0.99	0.99	0.99	0.99	0.99
Range of samples	105.5-466.0	113.5-466.0	105.5-433.0	111.5-347.5	108.5-415.0

Weighted Deming Regression Results of Afinion™ HDL Cholesterol Serum Results Compared to Siemens HDL Cholesterol Serum Results (pooled and per site).

	All	**Site 1**	**Site 2**	**Site 3**	**Site 4**
N	251	66	69	47	69
Intercept (mg/dL)	-2.1	-2.4	-0.9	-2.5	-3.0
Slope	1.04	1.05	1.02	1.05	1.04
Correlation coefficient (r)	0.98	0.98	0.99	0.98	0.99
Range of samples	23.2-92.7	27.0-88.8	23.2-88.8	30.9-88.8	27.0-92.7

Weighted Deming Regression Results of Afinion™ Triglyceride Serum Results Compared to Roche Triglyceride Serum Results (pooled and per site)

	All	**Site 1**	**Site 2**	**Site 3**	**Site 4**
N	246	65	69	45	67
Intercept (mg/dL)	-11.4	-7.5	-14.5	-13.0	-12.6
Slope	1.04	1.03	1.06	1.04	1.05
Correlation coefficient (r)	1.00	1.00	1.00	1.00	1.00
Range of samples	55.5-616.5	55.5-541.0	71.5-584.5	59.5-616.5	59.5-486.5

% Bias of Afinion Results at Medical Decision Points and Elevated Concentrations When Compared to the Predicate Device

Measurand	200 mg/dL	240 mg/dL	400 mg/dL	40 mg/dL	60 mg/dL	80 mg/dL	150 mg/dL	200 mg/dL	500 mg/dL
Cholesterol	1.3	1.7	2.4						
HDL				-1.6	0.1	1.0			
Triglyceride							-3.3	-1.4	2.0

b. Matrix comparison:

Not applicable, serum is the only sample type indicated

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The sponsor references the NCEPs recommendations for lipids testing and management (according to the ATP III report) in their labeling.

Reference Values

	[mg/dL]
LDL Cholesterol	
Optimal	< 100
Near optimal/ above optimal	100-129
Borderline high	130-159
High	160-189
Very high	≥ 190
Total Cholesterol	

Desirable	< 200
Borderline high	200-239
High	≥ 240
HDL Cholesterol	
Low	< 40
High	≥ 60
Serum Triglycerides	
Normal	< 150
Borderline high	150-199
High	200-499
Very high	≥ 500

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.