510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K232404

B Applicant

Medicon Hellas, S.A

C Proprietary and Established Names

CHOLESTEROL; HDL-Cholesterol; LDL-Cholesterol; TRIGLYCERIDES

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CHH	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	21 CFR 862.1175 - Cholesterol (Total) Test System	CH - Clinical Chemistry
LBS	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	21 CFR 862.1475 - Lipoprotein test system	CH - Clinical Chemistry
MRR	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	21 CFR 862.1475 - Lipoprotein test system	CH - Clinical Chemistry
CDT	Class I, meets the limitations of exemptions 21 CFR 862.9(c)(4)	21 CFR 862.1705 - Triglyceride test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New devices

B Measurand:

Cholesterol
HDL-Cholesterol
LDL-Cholesterol
Triglycerides

C Type of Test:

Quantitative, colorimetric assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

CHOLESTEROL: Reagent kit intended for the quantitative determination of cholesterol in human serum. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood, of lipid and lipoprotein metabolism disorders.

HDL-Cholesterol: Reagent kit intended for the quantitative determination of high-density lipoprotein in human serum. Measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

LDL-Cholesterol: Reagent kit intended for quantitative determination of low-density lipoprotein in human serum. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

TRIGLYCERIDES: Reagent kit intended for the quantitative determination of triglycerides (neutral fat) in human serum. Measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use only.

D Special Instrument Requirements:

For use on the Diatron Pictus 500 Clinical Chemistry Analyzer

IV Device/System Characteristics:

A Device Description:

The CHOLESTEROL test system is a one reagent system supplied in liquid ready-to-use form containing 4-Chlorophenol (4.7 mmol/L), 4-Aminoantipyrine (1 mmol/L), Cholesterol esterase (≥ 500 U/L), Cholesterol oxidase (CHOD, ≥ 500 U/L) and Peroxidase (POD, ≥ 500 U/L). Materials required but not provided within the assay kit: MEDICON Clinical Chemistry Control Level 1 and 2, and MEDI-CAL calibrator.

The HDL-Cholesterol test system is a one reagent system supplied in liquid ready-to-use form containing Cholesterol esterase (< 1500 U/L), Cholesterol oxidase (< 1000 U/L), Peroxidase (POD, < 1300 U/L), Ascorbate oxidase (< 3000 U/L), Accelerator (< 1 mM), N,N-bis(4-sulfobytul)-m-toluidine disodium (DSBmT, < 1 mM), and 4-aminoantipyrine (< 1 mM). Materials required but not provided within the assay kit: MEDICON Clinical Chemistry Control Level 1 and 2, and MEDICON HDL calibrator.

The LDL-Cholesterol test system is a two-reagent system supplied in liquid ready-to-use form. Reagent 1 (R1) contains Detergent 1 (< 1 %), 4-Aminoantipyrine (< 0.1 %), Cholesterol oxidase (<1500 U/L), Cholesterol esterase (< 2500 U/L), Peroxidase (POD, < 1300 U/L). Reagent 2 (R2) contains Ascorbic oxidase (< 3000 U/L), Detergent 2 (< 1%), and N,N-bis(4-sulfobytul)-m-toluidine disodium (DSBmT, <1 mM). Materials required but not provided within the assay kit: MEDICON Clinical Chemistry Control Level 1 and 2, and MEDICON LDL calibrator.

The TRIGLYCERIDES test system is a two-reagent system supplied in liquid ready-to-use form. Reagent 1 (R1) contains Pipes buffer (240 mM), Peroxidase (POD, > 5000 U/L), Glycerokinase (> 1000 U/L), Lipoprotein lipase (> 15000 U/L), Adenosine triphosphate (ATP, 4.5 mM) and N-Ethyl-N-(2-hydroxy-3-sulfopropyl)-3-methylaniline sodium salt (TOOS, 4.8 mM). Reagent 2 (R2) contains 4-Aminoantipyrine (< 15 mmol/L) and glycerol-3-phosphate-oxidase (GPO, > 55000 U/L). Materials required but not provided within the assay kit: MEDICON Clinical Chemistry Control Level 1 and 2, and MEDI-CAL calibrator.

B Principle of Operation:

The CHOLESTEROL test system uses the cholesterol oxidase peroxidase (CHOD-PAP) enzymatic colorimetric method. The cholesteryl esterase catalyzes the hydrolysis of cholesterol esters to cholesterol and free fatty acids. Free cholesterol, including that originally present in the sample, is then oxidized by the enzyme cholesterol oxidase to cholest-4-en-3-one, by using molecular oxygen as the electron acceptor and concurrently producing hydrogen peroxide (H_2O_2). The H_2O_2 produced is then used in a subsequent chromogenic oxidative coupling reaction, catalyzed by the enzyme peroxidase, in the presence of a redox indicator system, which leads to the formation of a colored compound, absorbing light at 550 nm. The increase in absorbance is directly proportional to the cholesterol concentration in the sample.

The HDL-Cholesterol test system uses the Accelerator Selective Detergent method. The determination of HDL-Cholesterol is based on the following reactions: LDL, VLDL, and chylomicrons are neutralized by the combined action of the enzymes Cholesterol Oxidase, Peroxidase, accelerators and DSBmT. HDL remaining in the sample is disrupted by the action of

a selective detergent and cholesterol is converted to Δ4 Cholestenone by the enzymatic action of Cholesterol Esterase and Cholesterol Oxidase, with the subsequent production of H_2O_2, which reacts with DSBmT and 4-aminoantipyrine in the presence of Peroxidase to a colored complex that absorbs light at 590 nm. The absorbance measured is proportional to the concentration of HDL-Cholesterol in the sample.

The LDL-Cholesterol test system uses the Selective Detergent method. The method is in a two-reagent format and depends on the properties of a unique detergent. The first detergent solubilizes only the non-LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non-color forming reaction. The second detergent solubilizes the remaining LDL particles, and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler at 590 nm produces color that is proportional to the amount of LDL cholesterol present in the sample.

The TRIGLYCERIDES test system uses the enzymatic glycerol-3-phosphate-peroxidase (GPO-POD) method. The method enzymatically hydrolyzes by lipase to free fatty acids and glycerol. Glycerol is phosphorylated by adenosine triphosphate (ATP) with glycerol kinase (GK) to produce glycerol-3- phosphate and adenosine diphosphate (ADP). Glycerol-3-phosphate-oxidase (GPO) oxidizes glycerol-3-phosphate to dihydroxyacetone phosphate and H_2O_2. The catalytic action of peroxidase (POD) forms quinoneimine from H_2O_2, aminoantipyrine and TOOS. The absorption change at 550 nm is proportional to the concentration of triglycerides in the sample.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Cholesterol: Olympus Cholesterol Reagent - K925603
HDL-Cholesterol: Direct HDL - K981224
LDL-Cholesterol: Direct LDL - K981303
Tryglycerides: Olympus Triglyceride Reagent - K063804

B Predicate 510(k) Number(s):

See section V(A) above.

C Comparison with Predicate(s):

Device & Predicate Device(s):	K232404	K925603
Device Trade Name	CHOLESTEROL	Olympus Cholesterol Reagent
General Device Characteristic Similarities		
Intended Use	Reagent intended for the quantitative determination of Cholesterol	Same
Sample Type	Serum	Same
General Device Characteristic Differences		

Device & Predicate Device(s):	K232404	K925603
Measuring Range	20 to 700 mg/dL	50 to 700 mg/dL

Device & Predicate Device(s):	K232404	K981224
Device Trade Name	HDL-Cholesterol	Direct HDL
General Device Characteristic Similarities		
Intended Use	Reagent intended for the quantitative determination of high-density lipoprotein.	Same
General Device Characteristic Differences		
Measuring Range	6 to 200 mg/dL	8 to 180 mg/dL
Sample Type	Serum	Serum or Plasma

Device & Predicate Device(s):	K232404	K981303
Device Trade Name	LDL-Cholesterol	Direct LDL
General Device Characteristic Similarities		
Intended Use	Reagent intended for the quantitative determination of low-density lipoprotein.	Same
General Device Characteristic Differences		
Measuring Range	3 to 800 mg/dL	1 to 600 mg/dL
Sample Type	Serum	Serum or Plasma

Device & Predicate Device(s):	K232404	K063804
Device Trade Name	TRIGLYCERIDES	Olympus Triglyceride Reagent
General Device Characteristic Similarities		
Intended Use	Reagent intended for the quantitative	Same

Device & Predicate Device(s):	K232404	K063804
	determination of triglycerides	
Measuring Range	10 to 1,000 mg/dL	Same
General Device Characteristic Differences		
Sample Type	Serum	Serum or Plasma

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) Guideline EP05-A3: User Protocol for Evaluation of Qualitative Test Performance.

CLSI Guideline EP06 2nd Edition: Evaluation of the Linearity of Quantitative Measurement Procedures.

CLSI Guideline EP07 3rd Edition: Interference Testing in Clinical Chemistry.

CLSI Guideline EP09c 3rd Edition: Measurement Procedure Comparison and Bias Estimation Using Patient Samples.

CLSI Guideline EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A precision study for each candidate assay was conducted following the recommendations in the CLSI EP05-A3 guideline. Precision was assessed using multiple levels of pooled serum samples, and tested in 2 replicates per run, 2 runs per day for 20 days for a total of 80 measurements per level. One operator conducted the study using one lot of reagents using one instrument. The results are summarized below for a single lot:

a. Repeatability (Within-run precision)

Analyte	Pool	Mean (mg/dL)	SD (mg/dL)	%CV
Cholesterol	Level 1	92	1.5	1.6
	Level 2	241	3.3	1.4
	Level 3	345	4.9	1.4
HDL-Cholesterol	Level 1	31	0.7	2.3
	Level 2	57	0.7	1.2
LDL-Cholesterol	Level 1	98	1.0	1.0
	Level 2	126	2.2	1.8

Analyte	Pool	Mean (mg/dL)	SD (mg/dL)	%CV
	Level 3	156	1.7	1.1
	Level 4	193	2.1	1.1
Triglycerides	Level 1	41	0.4	1.0
	Level 2	148	1.9	1.3
	Level 3	399	2.8	0.7

b. Between-run precision

Analyte	Pool	Mean (mg/dL)	SD (mg/dL)	%CV
Cholesterol	Level 1	92	0	0
	Level 2	241	4.9	2.0
	Level 3	345	2.9	0.8
HDL-Cholesterol	Level 1	31	0.6	2.0
	Level 2	57	0.4	0.8
LDL-Cholesterol	Level 1	98	1.2	1.2
	Level 2	126	2.9	2.3
	Level 3	156	2.3	1.5
	Level 4	193	3.1	1.6
Triglycerides	Level 1	41	0.6	1.6
	Level 2	148	3.1	2.1
	Level 3	399	5.2	1.3

c. Within-laboratory precision

Analyte	Pool	Mean (mg/dL)	SD (mg/dL)	%CV
Cholesterol	Level 1	92	2.1	2.3
	Level 2	241	6.9	2.9
	Level 3	345	10.3	3.0
HDL-Cholesterol	Level 1	31	1.2	3.8
	Level 2	57	1.5	2.6
LDL-Cholesterol	Level 1	98	3.8	3.9
	Level 2	126	4.4	3.5
	Level 3	156	5.6	3.6
	Level 4	193	6.1	3.2
Triglycerides	Level 1	41	0.9	2.1
	Level 2	148	4.5	3.0
	Level 3	399	7.2	1.8

2. Linearity:

A linearity study for each candidate assay was conducted following the recommendations in the CLSI EP06 2nd Edition guideline. The linearity was assessed using pooled serum samples spanning the target analyte concentration range which were prepared by serial dilution of a known high-level sample. A total of 11 to 13 samples were prepared for the linearity assessment. For each sample, four replicates were tested by one operator using one

instrument. The mean values of four replicates of each pool were compared to the expected target values to determine the deviation from linearity. For all samples, the deviation from linearity was less than 7%. The linear regression results are given in the table below for a single new lot:

Analyte	Slope	Intercept	R^2
Cholesterol	1.001	0.409	0.9997
HDL-Cholesterol	1.033	-0.668	0.9984
LDL-Cholesterol	1.009	-0.400	0.9996
Triglycerides	0.978	-0.236	0.9994

3. Analytical Specificity/Interference:
An interference study for each candidate assay was evaluated following the recommendations in the CLSI EP07 3rd Ed. guideline. Serum samples at two analyte concentrations near the medical decision concentrations were evaluated for each substance. The samples were divided into two aliquots: control with no added interferent and test with added interferent. Each sample was measured in two replicates. The study tested for possible interference from common endogenous substances, and exogenous substances such as medications or supplements likely to be used by the target patient population. The following tables list the concentration of each substance at which no significant interference was detected; defined as a difference of less than or equal ±10% between the test sample and control.

Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Acetaminophen	15.6 mg/dL
N-Acetylcysteine	15 mg/dL
Acetylsalicylic Acid	3.0 mg/dL
Ampicillin	7.5 mg/dL
L-Ascorbic acid	5.25 mg/dL
Atorvastatin	0.075 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Calcium Dobesilate	6 mg/dL
Cefotaxime	52.8 mg/dL
Cefoxitin	660 mg/dL
Cyclosporine	0.18 mg/dL
Dipyrone	3.3 mg/dL
Dobutamine	0.121 mg/dL
Doxycycline	1.8 mg/dL
Fenofibrate	4.5 mg/dL
Hemoglobin	500 mg/dL
Heparin	330 U/dL
Ibuprofen	21.9 mg/dL

Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Intralipid	2000 mg/dL
Levodopa	0.75 mg/dL
Methotrexate	136 mg/dL
Methyldopa	2.25 mg/dL
Metronidazole	12.3 mg/dL
Phenylbutazone	32.1 mg/dL
Pravastatin	0.0207 mg/dL
Rifampicin	4.8 mg/dL
Rosuvastatin	0.111 mg/dL
Simvastatin	0.168 mg/dL
Theophylline	6 mg/dL
Triglycerides	1500 mg/dL

HDL-Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Acetaminophen	15.6 mg/dL
N-Acetylcysteine	15 mg/dL
Acetylsalicylic Acid	3 mg/dL
Ampicillin	7.5 mg/dL
L-Ascorbic acid	5.25 mg/dL
Atorvastatin	0.075 mg/dL
Bilirubin (conjugated)	40.0 mg/dL
Bilirubin (unconjugated)	40.0 mg/dL
Calcium Dobesilate	6 mg/dL
Cefotaxime	52.8 mg/dL
Cefoxitin	660 mg/dL
Cyclosporine	0.18 mg/dL
Dipyrone	3.3 mg/dL
Dobutamine	0.121 mg/dL
Doxycycline	1.8 mg/dL
Fenofibrate	4.5 mg/dL
Hemoglobin	1000 mg/dL
Heparin	330 mg/dL
Ibuprofen	21.9 mg/dL
Intralipid	2000 mg/dL
Levodopa	0.75 mg/dL

HDL-Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Methotrexate	136 mg/dL
Methyldopa	1.35 mg/dL
Metronidazole	12.3 mg/dL
Phenylbutazone	32.1 mg/dL
Pravastatin	0.0207 mg/dL
Rifampicin	4.8 mg/dL
Rosuvastatin	0.111 mg/dL
Simvastatin	0.168 mg/dL
Theophylline	6.0 mg/dL
Triglycerides	1500 mg/dL

LDL-Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Acetaminophen	15.6 mg/dL
N-Acetylcysteine	15 mg/dL
Acetylsalicylic Acid	3 mg/dL
Substance tested	Highest concentration tested at which no significant interference was observed
Ampicillin	7.5 mg/dL
L-Ascorbic acid	5.25 mg/dL
Atorvastatin	0.075 mg/dL
Bilirubin (conjugated)	40.0 mg/dL
Bilirubin (unconjugated)	40.0 mg/dL
Calcium Dobesilate	6 mg/dL
Cefotaxime	52.8 mg/dL
Cefoxitin	660 mg/dL
Dipyrone	3.3 mg/dL
Dobutamine	0.121 mg/dL
Doxycycline	1.8 mg/dL
Fenofibrate	4.5 mg/dL
Hemoglobin	1000 mg/dL
Ibuprofen	21.9 mg/dL
Intralipid	1500 mg/dL
Levodopa	0.75 mg/dL
Methotrexate	136 mg/dL
Methyldopa	2.25 mg/dL

LDL-Cholesterol	
Substance tested	Highest concentration tested at which no significant interference was observed
Metronidazole	12.3 mg/dL
Phenylbutazone	32.1 mg/dL
Pravastatin	0.0207 mg/dL
Rifampicin	4.8 mg/dL
Rosuvastatin	0.0111 mg/dL
Simvastatin	0.168 mg/dL
Theophylline	6.0 mg/dL
Triglycerides	3000 mg/dL

Triglycerides	
Substance tested	Highest concentration tested at which no significant interference was observed
Acetaminophen	15.6 mg/dL
N-Acetylcysteine	15 mg/dL
Acetylsalicylic Acid	3 mg/dL
Ampicillin	7.5 mg/dL
L-Ascorbic acid	5.25 mg/dL
Atorvastatin	0.075 mg/dL
Bilirubin (conjugated)	40 mg/dL
Bilirubin (unconjugated)	40 mg/dL
Calcium Dobesilate	6 mg/dL
Substance tested	Highest concentration tested at which no significant interference was observed
Cefotaxime	52.8 mg/dL
Cefoxitin	660 mg/dL
Dipyrone	3.3 mg/dL
Dobutamine	15.6 mg/dL
Doxycycline	1.8 mg/dL
Fenofibrate	4.5 mg/dL
Hemoglobin	400 mg/dL
Ibuprofen	21.9 mg/dL
Levodopa	0.75 mg/dL
Methotrexate	136 mg/dL
Methyldopa	1.575 mg/dL
Metronidazole	12.3 mg/dL
Phenylbutazone	32.1 mg/dL
Pravastatin	0.0207 mg/dL

Triglycerides	
Substance tested	Highest concentration tested at which no significant interference was observed
Rifampicin	4.8 mg/dL
Rosuvastatin	0.0111 mg/dL
Simvastatin	0.168 mg/dL
Theophylline	6.0 mg/dL

4. Assay Reportable Range:

The reportable ranges for each analyte are given in the table below:

Analyte	Reportable Range (mg/dL)
Cholesterol	25 to 700
HDL-Cholesterol	6 to 180
LDL-Cholesterol	3 to 800
Triglycerides	10 to 1000

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability
The candidate assays and their respective calibrators are traceable to NIST standard reference materials (SRM 1952a, SRM 1951c and SRM 909c).

On-Board Stability
The stability protocols and acceptance criteria were reviewed and determined to be adequate. All reagents demonstrated on-board stability of 28 days.

6. Detection Limit:

Protocols for the determination of the limit of blank (LoB), the limit of detection (LoD) and the limit of quantification (LoQ) were performed in accordance with the recommendations in the CLSI Guideline EP17-A2. The LoB and LoD studies were carried out using blanks and low-level samples (60 each) over 3 days. The LoQ study used 10 serum samples that spanned the low end of linearity that were measured 5 times per day over 3 days for a total of 150 measurements per sample. The studies were performed on one Diatron Pictus 500 Clinical Chemistry Analyzer.

The resulting LoB, LoD and LoQ for the four measurands are summarized below:

Analyte	LoB (mg/dL)	LoD (mg/dL)	LoQ (mg/dL)
Cholesterol	2.5	4.4	4.6
HDL-Cholesterol	1.0	3.0	5.8
LDL-Cholesterol	1.0	2.0	3.0
Triglycerides	4.0	5.5	9.7

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

To establish the accuracy of the Medicon Hellas assays, a method comparison study was conducted to evaluate the analytical agreement to a comparator method for each of the 4 analytes. Serum samples were tested in singlicate on the Diatron PICTUS 500 Analyzer and the comparators. The results of the method comparison studies are summarized as follows:

Regression Analysis

Analyte	N	Slope	Intercept	R^2	Range (mg/dL)
Cholesterol	93	0.9769	5.098	0.999	44 to 666
HDL-Cholesterol	141	1.018	-0.028	0.997	6 to 177
LDL-Cholesterol	107	0.9821	1.750	0.999	5 to 721
Triglycerides	163	0.999	2.041	0.999	26 to 975

Predicted Bias at Medical Decision Points
An estimate of the predicated bias at the medical decision points was calculated as the percent difference between the regression line and the unity line at each medical decision point.

Analyte	Medical Decision Point	%Bias (95% CI)
Cholesterol	90 mg/dL	3.4 % (1.4 to 5.1 %)
	240 mg/dL	-0.2 % (-0.7 to 0.4 %)
	260 mg/dL	-0.3 % (-0.9 to 0.3 %)
	350 mg/dL	-0.9 % (-1.4 to -0.1 %)
HDL-Cholesterol	35 mg/dL	1.8 % (0.6 to 2.9 %)
	60 mg/dL	1.8 % (1.2 to 2.4 %)
LDL-Cholesterol	100 mg/dL	-0.0 % (-0.7 to 0.8 %)
	130 mg/dL	-0.4 % (-1.2 to 0.8 %)
	160 mg/dL	-0.7 % (-1.5 to 0.1 %)
	190 mg/dL	-0.9 % (-1.8 to 0.0 %)
Triglycerides	40 mg/dL	-2.8 % (1.0 to 4.9 %)
	150 mg/dL	-0.9 % (-1.3 to -0.4 %)
	400 mg/dL	-1.8 % (-2.2 to -1.1 %)

2. Matrix Comparison:

Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

The expected values for total cholesterol, HDL cholesterol, and triglycerides were identified in the labeling as:

Analyte	Concentration (mg/dL)	Adult Classification
Cholesterol	< 200	Desirable Levels
	200 - 239	Marginally High Levels
	> 239	Undesirable Levels

Source: National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 01-3670, May 2001.

Analyte	Concentration (mg/dL)	Adult Classification
HDL Cholesterol	≤ 40	High Risk
	≥ 60	Low Risk

Source: National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Third Report of the NCEP Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) final report. Circulation 2002; 106:3143-3421.

Analyte	Concentration (mg/dL)	Adult Classification
LDL Cholesterol	< 100	Optimal
	100 - 129	Near or above optimal
	130 - 159	Borderline high

Analyte	Concentration (mg/dL)	Adult Classification
	160 - 189	High
	≥ 190	Very High

Source: National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 01-3670, May 2001.

Analyte	Concentration (mg/dL)	Adult Classification
Triglycerides	< 150	Normal
	150 - 199	Borderline high
	200 - 499	High
	≥ 500	Very high

Source: National Cholesterol Education Program. Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). National Institutes of Health, National Heart, Lung, and Blood Institute, NIH Publication No. 01-3670, May 2001.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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