510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K223179

B Applicant

Alere San Diego, Inc.

C Proprietary and Established Names

Cholestech LDX ™ System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CGA	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry
CHH	Class I	21 CFR 862.1175 - Cholesterol (total) test system	CH - Clinical Chemistry
JGY	Class I	21 CFR 862.1705 - Triglyceride test system	CH - Clinical Chemistry
JJE	Class I	21 CFR 862.2160 - Discrete photometric chemistry analyzer for clinical use	CH - Clinical Chemistry
LBS	Class I	21 CFR 862.1475 - Lipoprotein test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification of a previously cleared device

B Measurand:

Total cholesterol (TC)
High-density lipoprotein (HDL)
Triglycerides (TRG)
Glucose (GLU)

C Type of Test:

Quantitative, enzymatic photometric

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The Cholestech LDX™ System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only and should not be used for testing in children under the age of 2 years. The Cholestech LDX™ System is comprised of the Cholestech LDX Analyzer and the following cassettes:

The Lipid Profile•GLU cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. The TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are also reported.

The TC•HDL•GLU cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, and glucose in whole blood.

The TC•GLU cassette is for the quantitative determination of total cholesterol and glucose in whole blood.

The Lipid Profile cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, and triglycerides in whole blood. The TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are also reported.

The TC•HDL cassette is for the quantitative determination of total cholesterol and HDL (high-density lipoprotein) cholesterol in whole blood.

The TC cassette is for the quantitative determination of total cholesterol in whole blood.

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

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

• Triglyceride 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.

• Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

Limitation – Cholestech LDX™ is not for use in children under the age of 2 years or patients with hyperbilirubinemia (Elevated bilirubin levels).

D Special Instrument Requirements:

Cholestech LDX™ Analyzer.

IV Device/System Characteristics:

A Device Description:

The Cholestech LDX™ System is a small, portable analyzer and test cassette system. The system is for in vitro diagnostic use only. The Analyzer uses reflectance photometry (the amount of light reflected from a solid surface) to determine the amount of the analyte in blood. The analyzer measures color changes of the four reagent pads. The amount of color formed is converted by the analyzer to a concentration and the results are shown on the liquid crystal display (LCD) screen. The assays for use on the Analyzer include total cholesterol (TC), high-density lipoprotein cholesterol (HDL), triglycerides (TRG), glucose (GLU), and by calculation, low-density lipoprotein (LDL), non-HDL cholesterol, and total cholesterol/HDL cholesterol ratio.

The modification that is the subject of this submission addresses revised bilirubin interference claims for all analytes (see Section VII.A.3.) and includes a new limitation and a software upgrade to mitigate the modified risks. The revised limitations consist of the statement "Cholestech LDX™ is not for use in children under the age of 2 years or patients with hyperbilirubinemia (Elevated bilirubin levels)". The software upgrade incorporates the revised limitations, displaying it on the Cholestech LDX™ analyzer screen, printing it on all paper test results, and presenting it on all results sent to the electronic medical record.

B Principle of Operation:

The Cholestech LDX™ System principle of operation has not changed since the review of K120615.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Alere Cholestech LDX Analyzer, Alere Cholestech LDX Lipid Profile - GLU Cassette

B Predicate 510(k) Number(s):
K120615

C Comparison with Predicate(s):

Device & Predicate Device(s):	K223179	K120615
Device Trade Name	Cholestech LDX™ System (Modified)	Cholestech LDX Analyzer and Cholestech LDX Lipid Profile•GLU Cassette
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the quantitative determination of total cholesterol, HDL cholesterol, triglycerides, and glucose in whole blood.	Same
Sample Type	Venous and Capillary Whole Blood	Same
Type of Use	For professional in vitro diagnostic use only	Same
General Device Characteristic Differences		
Limitations	To address revised interference claims from conjugated and unconjugated bilirubin, the modified device includes the following limitation "Cholestech LDX™ is not for use in children under the age of 2 years or patients	Does not include the limitation

Device & Predicate Device(s):	K223179	K120615
	with hyperbilirubinemia (Elevated bilirubin levels)".	

VI Standards/Guidance Documents Referenced:

CLSI – EP07-A3 – Interference Testing in Clinical Chemistry – 3rd edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

2. Linearity:
   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

3. Analytical Specificity/Interference:
   Interference testing was performed based on guidance from CLSI EP07-A3 and a study evaluating two interferents*, conjugated and unconjugated bilirubin was conducted. For the study, target analytes at different concentrations; triglycerides (100 mg/dL and 250 mg/dL), HDL (30 mg/dL and 80 mg/dL), glucose (50-70 mg/dL, 110-130 mg/dL and 225-270 mg/dL), total cholesterol (150 mg/dL and 220 mg/dL) were created in pooled samples that were spiked with the interferents, conjugated and unconjugated bilirubin, at a range of concentrations. Samples were tested in replicates of sixteen (16) using three (3) Cholestech LDX™ Lipid Profile Glucose test cassettes, on sixteen (16) Cholestech LDX™ Analyzers. The following table list the concentration of each substance at which no significant interference was detected; defined by the sponsor as a difference of less than or equal to ±10% between the test sample and control:

Analyte	Analyte Target Values	Highest concentration with no observed Unconjugated Bilirubin Interference (mg/dL)	Highest concentration with no observed Conjugated Bilirubin Interference (mg/dL)
Total Cholesterol	150 mg/dL ± 10%	7.5	10
	220 mg/dL ± 10%	7.5	12.5
Triglycerides	100 mg/dL ± 10%	5	3.75
	250 mg/dL ± 10%	5	7.5
	30 mg/dL ± 10%	2.5	2.5

Analyte	Analyte Target Values	Highest concentration with no observed Unconjugated Bilirubin Interference (mg/dL)	Highest concentration with no observed Conjugated Bilirubin Interference (mg/dL)
HDL	80 mg/dL ± 10%	5	12.5
Glucose	50-70 mg/dL	10	12.5
	110-130 mg/dL	20	15
	225-270 mg/dL	27.1	35

Potential interference from conjugated and unconjugated bilirubin was also estimated for the calculated parameters.

Based on the data, the sponsor updated the interference claims in their labeling for the test system for conjugated and unconjugated bilirubin to indicate that concentrations up to 2.5 mg/dL do not interfere with the test system.

*Other aspects of this performance characteristic (including additional interferent testing) were established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296, K904082 and K120615.

4. Assay Reportable Range:

   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

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

   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

6. Detection Limit:

   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

2. Matrix Comparison:

   This performance characteristic was established in the previous 510(k) submissions, reviewed under K901900, K912136, K914469, K922612, K932727, K914033, K905296 and K904082.

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 Cholestech LDX™ System's expected values/reference range has not changed since the review of K120615.

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.