September 20, 2023

Alere San Diego, Inc.
Nathifa Bradshaw
Manager, Regulatory Affairs
9942 Mesa Rim Road
San Diego, California 92121

Re: K223179
Trade/Device Name: Cholestech LDX ™ System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: CGA, CHH, LBS, JGY, JJE
Dated: June 6, 2023
Received: June 6, 2023

Dear Nathifa Bradshaw:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223179

Device Name
Cholestech LDX™ System

Indications for Use *(Describe)*
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.

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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5 510(K) SUMMARY

The following 510(k) Summary was prepared in accordance with 21 CFR 807.92

5.1 General Information

Document #: k223179 & CW220017

Type of 510(k): Dual Submission- 510(k) and CLIA Waiver

Applicant Name: Alere San Diego, Inc.
9942 Mesa Rim Rd
San Diego, California 92121
United States

Establishment Registration: #2027969

Company Contact: Nathifa Bradshaw
Regulatory Affairs Manager
Phone: +1-561-428-2203
Email: nathifa.bradshaw@abbott.com

Date Prepared: September 19, 2023

5.2 Device Identification

Device Common Name Glucose and Cholesterol (total) test system

Device Trade Name Cholestech LDX™ System

Classification:

Product Code	Classification	Regulation Section	Classification Panel
CGA	Class II	21 CFR 862.1345	Clinical Chemistry
CHH	Class I	21 CFR 862.1175	Clinical Chemistry
JGY	Class I	21 CFR 862.1705	Clinical Chemistry
JJE	Class I	21 CFR 862.2160	Clinical Chemistry
LBS	Class I	21 CFR 862.1475	Clinical Chemistry

Predicate Device: Cholestech LDX™ System (k120615)

The following are the legally marketed devices covered under the predicate device clearance, k120615, and their prior clearances:

The original Cholestech LDX™ lipid monitoring system was cleared under premarket notification k901900 for use with Cholestech LDX™ analyzer.

In addition to total cholesterol, the analytes glucose, HDL, triglycerides were cleared under premarket notification k932727.

The Cholestech multianalyte controls and calibration verification materials were originally cleared under premarket notification k102700.

Cholestech LDX™ software update to incorporate a humidity sensor was cleared under premarket notification k120615.

5.3 Device Description

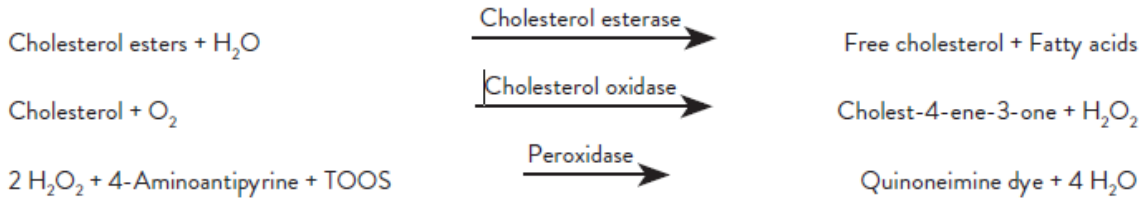
The Cholestech LDX™ system combines enzymatic methodology and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides and glucose. Samples used for testing can be whole blood from a fingerstick (collected in a lithium heparin-coated capillary tube) or venipuncture. The sample is applied to the Cholestech LDX™ cassette[a].

The cassette is then placed into the Cholestech LDX™ Analyzer where a unique system on the cassette separates the plasma from the blood cells. A portion of the plasma flows to the right side of the cassette and is transferred to both the total cholesterol and triglyceride reaction pads. Simultaneously, plasma flows to the left side of the cassette where the low- and very low-density lipoproteins (LDL and VLDL) are precipitated with dextran sulfate (50,000 MW) and magnesium acetate precipitating reagent.The filtrate, containing both glucose and HDL cholesterol, is transferred to both the glucose and HDL cholesterol reaction pads.

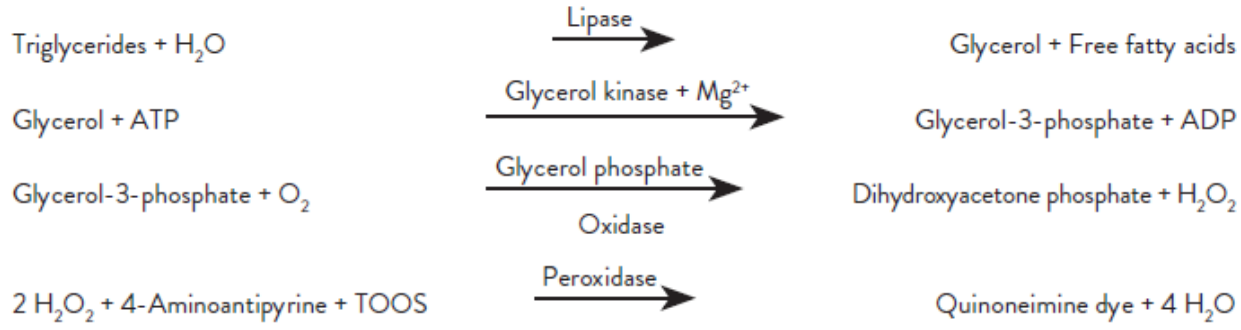
The Cholestech LDX™ Analyzer measures total cholesterol and HDL cholesterol by an enzymatic method based on the method formulation of Allain et al, and Roeschlau. Cholesterol esterase hydrolyzes the cholesterol esters in the filtrate or plasma to free cholesterol and the corresponding fatty acid. Cholesterol oxidase, in the presence of oxygen, oxidizes free cholesterol to cholest-4-ene-3-one and hydrogen peroxide. In a reaction catalyzed by horseradish peroxidase, the peroxide reacts with 4-

[a] In this submission Cholestech LDX™ cassette refers to all six available configurations as indicated in the Package Insert.

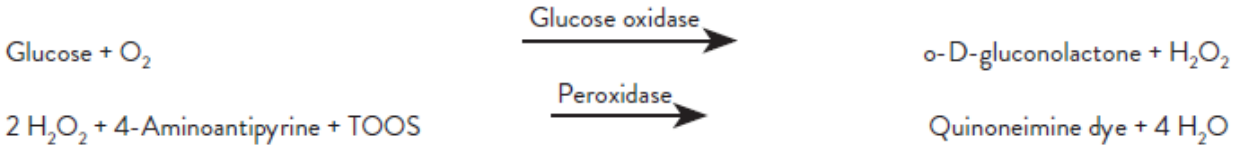
Aminoantipyrine and N-ethyl-N-sulfohydroxypropyl-m-toluidine, sodium sale (TOOS) to form a purple-colored quinoneimine dye proportional to the total cholesterol and HDL cholesterol concentrations of the sample.



The analyzer measures triglycerides by an enzymatic method based on the hydrolysis of triglycerides by lipase to glycerol and free fatty acids. Glycerol, in a reaction catalyzed by glycerol kinase, is converted to glycerol-3-phosphate. In a third reaction, glycerol-3-phosphate is oxidized by glycerol phosphate oxidase to dihydroxyacetone phosphate and hydrogen peroxide. The color reaction utilizing horseradish peroxidase is the same as for the total cholesterol and HDL cholesterol. Estimated LDL cholesterol and non-HDL cholesterol and a TC/HDL ratio are calculated using the measured values for TC, HDL, and Triglycerides.



The analyzer measures glucose by an enzymatic method that uses glucose oxidase to catalyze the oxidation of glucose to gluconolactone and hydrogen peroxide. The color reaction utilizing horseradish peroxidase is the same as that for total cholesterol, HDL cholesterol and triglycerides. The resultant color in all the reactions is measured by reflectance photometry.



A brown (magnetic) stripe on each cassette contains the calibration information required for the Cholestech LDX™ Analyzer to convert the reflectance reading (% R) to the total cholesterol, HDL cholesterol, triglycerides and glucose concentrations.

5.4 Intended Use/Indications 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.

5.5 Comparison with Predicate

Attribute	Predicate Device – k120615 Cholestech LDX™ analyzer and Cholestech Lipid Profile•GLU Cassette	Candidate Device-k223179 Modified Cholestech LDX™ System
Similarities		
Assay principle	The Cholestech LDX™ System combines enzymatic methodology5 and solid-phase technology to measure total cholesterol, HDL cholesterol, triglycerides and glucose. Samples used for testing can be whole blood from a fingerstick (collected in a lithium heparin-coated capillary tube) or venipuncture. The sample is applied to an Cholestech LDX™ cassette.	Same
Sample Type	Whole blood	Same
Analyzer	Cholestech LDX™ analyzer	Same
User Interface	User display and operating instructions in labeling	Same

Attribute	Predicate Device – k120615 Cholestech LDX™ analyzer and Cholestech Lipid Profile•GLU Cassette	Candidate Device-k223179 Modified Cholestech LDX™ System
Warning and Precautions	For professional in vitro diagnostic use only. All blood samples, containers, capillary tubes and materials that have come in contact with blood should be handled as if capable of transmitting infectious disease and discarded into a biohazardous waste container after use.	Same
Differences		
Intended Use	The Alere Cholestech LDX™ System is a small, portable analyzer and test cassette system. The System is for in vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Alere Cholestech LDX ™ Analyzer.	The CholestechLDX ™ System is a small, portable analyzer and test cassette system. The system is for In Vitro diagnostic use only. The Lipid Profile•GLU Cassette is for the quantitative determination of total cholesterol, HDL (high-density lipoprotein) cholesterol, triglycerides and glucose in whole blood. A TC/HDL (total cholesterol/HDL cholesterol) ratio and estimated values for LDL (low-density lipoprotein) and non-HDL cholesterol are calculated by the Cholestech LDX ™ analyzer. Cholestech LDX ™ system should not be used for testing in children under the age of 2 years. The Cholestech LDX™

Attribute	Predicate Device – k120615 Cholestech LDX™ analyzer and Cholestech Lipid Profile•GLU Cassette	Candidate Device-k223179 Modified Cholestech LDX™ System
	• 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, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.	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

Attribute	Predicate Device – k120615 Cholestech LDX™ analyzer and Cholestech Lipid Profile•GLU Cassette	Candidate Device-k223179 Modified Cholestech LDX™ System
		(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.
Limitations	Some substances may cause inaccurate results with enzymatic tests. The substances listed below were tested for interference with all analytes. Less than	Some substances may cause inaccurate results with enzymatic tests. The substances listed below were tested for interference

<table>
<tr><th>Attribute</th><th>Predicate Device – k120615
Cholestech LDX™ analyzer and
Cholestech Lipid Profile•GLU Cassette</th><th>Candidate Device-k223179
Modified Cholestech LDX™ System</th></tr>
<tr><td></td><td>10% interference was seen at the levels shown.

Substance Concentration (mg/dL)

Ascorbic Acid 1

Hemoglobin 125

Bilirubin 5

Lactose 100

Creatinine 30

Lovastatin (Mevacor) 4

Cysteine 10

Nicotinic Acid (Niacin) 10

Fructose 30

Urea 500

Gemfibrozil (Lopid)15

Uric Acid 15

Glutathione 1

• Hematocrits between 30% and 49% do not affect results.

• Blood collection tubes with glycerol should not be used for the triglyceride test.

• Hand creams and soaps with glycerol may cause falsely high triglyceride results.</td><td>with all analytes. Less than 10% interference was seen at the levels shown.

Substance Concentration (mg/dL)

<table>
<tr><td>Ascorbic Acid</td><td>1</td><td>Glutathione</td><td>1</td></tr>
<tr><td>Conjugated Bilirubin</td><td>2.5</td><td>Hemoglobin</td><td>125</td></tr>
<tr><td>Unconjugated Bilirubin</td><td>2.5</td><td>Lactose</td><td>100</td></tr>
<tr><td>Creatinine</td><td>30</td><td>Lovastatin (Mevacor)</td><td>4</td></tr>
<tr><td>Cysteine</td><td>10</td><td>Nicotinic Acid (Niacin)</td><td>10</td></tr>
<tr><td>Fructose</td><td>30</td><td>Urea</td><td>500</td></tr>
<tr><td>Gemfibrozil (Lopid)</td><td>15</td><td>Uric Acid</td><td>15</td></tr>
</table>

• Hematocrits between 30% and 49% do not affect results.

• Blood collection tubes with glycerol should not be used for the triglyceride test.

• Hand creams and soaps with glycerol may cause falsely high triglyceride results.

• The triglyceride test measures triglycerides and free glycerol. Free glycerol usually is less than 20 mg/dL.

• There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.</td></tr>
</table>

Attribute	Predicate Device – k120615 Cholestech LDX™ analyzer and Cholestech Lipid Profile•GLU Cassette	Candidate Device-k223179 Modified Cholestech LDX™ System
	• The triglyceride test measures triglycerides and free glycerol. Free glycerol usually isless than 20 mg/dL. • There may be a 6–7% difference in the glucose levels of fingerstick and venous blood.	

5.6 Technological Characteristics

Cholestech LDX™ system maintains the same intended use and indications for use. The principle of operations, and chemical composition remains unchanged.

5.7 Description of Device Modification

The modification to the labeling of the Cholestech LDX™ system is to update the performance claim of the device as it pertains to interference level of conjugated and unconjugated Bilirubin. The population of the intended use of the device has been further specified to indicate that the system should not be used for testing in children under the age of 2 years; and for Glucose measurements, to remove use in neonatal hypoglycemia.

5.8 Design Control Activities

The verification studies of the device modification have been performed under design control. The design control activities were based on risk analysis, and acceptance criteria were set to maintain the performance and safety of the Cholestech LDX™ system.
The risk analysis identified the appropriate in-house analytical performance verification studies to demonstrate that the analytical performance and risk of erroneous results for Cholestech LDX™ system are not adversely affected by using the proposed modification device.

5.9 Conclusion

Verification studies were performed as required by risk analysis and all acceptance criteria were met. The technological characteristics of the predicate device cleared under k120615 are the same as the modified device, and the system maintains the same

intended use and indications for use as the predicate device. In addition, the update to the Bilirubin Interference claim and further specification of the population in the indications for use/intended use did not raise new or different questions of safety and effectiveness; therefore, the Cholestech LDX ™ system is found to be substantially equivalent to the predicate device.