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: K032027.

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Cholestech Corporation
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Contact: Thomas E. Worthy, PhD.
Vice President, Research and Regulatory Affairs
Cholestech Corporation.

Summary Date: June 30, 2003

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): Cholestech LDX aspartate aminotransferase (AST)

Name (usual): Colorimetric assay for the determination of aspartate amino transferase (SGOT/AST)

Classification: 21 CFR 862.1100, Class II, CIS (75)

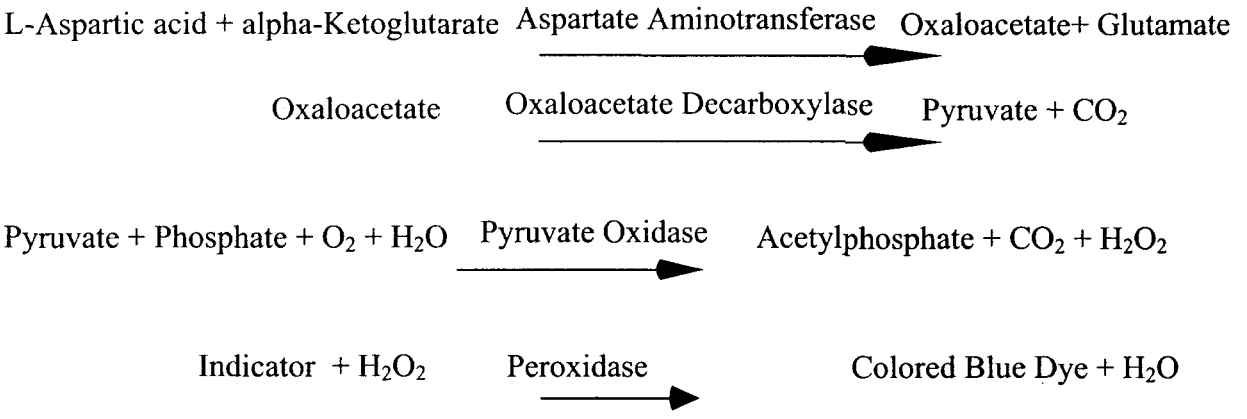
Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

LDX AST is substantially equivalent to the Synchron CX® AST system (Synchron CX, Beckman Coulter, Inc., Fullerton, CA). The LDX AST method is identical or similar to its predicate in terms of: intended use, measurement principle (enzymatic reactions), measurement (assay) range, specimen type, and the requirement for an analyzer.

Description of Device (21 CFR 807.92 (a)(4))

The Cholestech LDX System combines enzymatic methodology and solid-phase technology to measure AST. Samples used for testing can be whole blood from a fingerstick (collected in a lithium heparin coated capillary tube), venous whole blood or serum. The sample is applied to a Cholestech LDX AST cassette. The cassette is then placed into the Cholestech LDX Analyzer where a unique system on the cassette separates the plasma from the blood cells. The plasma flows to both sides of the cassette and is transferred to the AST reaction pad.

The Cholestech LDX Analyzer measures Aspartate aminotransferase by an enzymatic method based on the method formulation of Katsuyama et al.[1,2] Aspartic acid aminotransferase catalyzes the transfer of amino groups from L-Aspartic acid to alpha-Ketoglutarate producing oxaloacetate and glutamate. Oxaloacetate Decarboxylase converts the Oxaloacetate to Pyruvate by the removal of CO_2. Pyruvate oxidase, in the presence of oxygen, oxidizes the pyruvate to acetylphosphate and hydrogen peroxide. In a reaction catalyzed by horseradish peroxidase, the peroxide reacts with an indicator dye to form a blue color at a rate proportional to the AST concentration of the sample. The resultant color in the reaction 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 to the AST concentration in U/L, 37°C.

Intended Use (21 CFR 807.92 (a)(5))

The Cholestech LDX aspartate aminotransferase (AST) test is for the in vitro quantitative determination of aspartate aminotransferase (AST) in whole blood or serum on the Cholestech LDX Analyzer. AST measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis), and heart diseases.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between the LDX AST and the predicate device follows.

Comparison Table:
Cholestech LDX AST vs Beckman Coulter Synchron CX AST

Device Name	LDX AST (new device)	Synchron CX® AST (K952427)
Indications for use	The Cholestech LDX aspartate aminotransferase (AST) test is for the in vitro quantitative determination of AST in whole blood or serum on the Cholestech LDX Analyzer. AST measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis), and heart diseases.	The Synchron CX reagent, in conjunction with the Synchron ® Enzyme Validator Set, is intended for the quantitative determination of AST activity in serum or plasma on Synchron CX Clinical Systems. AST measurements are used in the diagnosis and treatment of certain types of liver and heart diseases.
Instrument Required	LDX Analyzer	Synchron CX Clinical System
Technology	Enzymatic methodology and a solid-phase technology	Enzymatic rate method; appropriate sample and reagent volumes are introduced to the system's cuvette.
Assay Range	10 to 400 U/L	5 to 400 U/L
Sample Type	Whole blood (capillary and venous) and serum	Serum or plasma
Calibration Requirements	No calibration performed by the user; test information is encoded on the magnetic stripe of the cassette, and the stripe is read by the LDX Analyzer each time a cassette is run.	Calibration required via the use of the Synchron Enzyme Validator Set; under typical operating conditions, the AST reagent cartridge must be calibrated every 5 days, and also with certain parts replacement or maintenance procedures.
Testing	Professional-Use, point-of-care	Professional-Use, conventional laboratory

Device Name	LDX AST (new device)	Synchron CX® AST (K952427)
Environment		

Brief Discussion of Nonclinical and Clinical Performance Data (21 CFR 807.92(b)(1,2, 3))

- Assay range: 10 – 400 U/L
- Hematocrit tolerance: up to 50%
- Interference testing: less than 10% interference when challenged by evaluated levels of endogenous and exogenous (therapeutic) substances
- Precision: 2 levels of Controls (Low- ~31 U/L AST, and High- ~106 U/L AST) were tested in duplicate, twice a day, over a 20 day period for a total of 80 replicates per level. The percent coefficient of variation (%CV) from the testing of the Low Control was 8.8%, and 4.4% from the testing of the High Control. When the same testing protocol was performed with a whole blood sample at 58 U/L, the %CV was 4.8%.
- Accuracy: The LDX AST test was compared to the Synchron CX AST test with 109 matched serum samples. The comparative data appear below (Synchron CX on x-axis).

LDX AST vs Synchron CX AST

n	slope	y-intercept	"r"	Range of Values
109	0.97	1.6	0.983	12 – 396 U/L

A study was performed where results obtained from testing whole blood samples (both venous and fingerstick) on the LDX were compared to results obtained from testing matched serum samples on the LDX. The comparative data appear below (serum results on x-axis).

LDX AST: venous whole blood samples vs serum samples

n	slope	y-intercept	"r"	Range of Values
46	1.08	0.3	0.998	13 - 343 U/L

LDX AST: fingerstick whole blood samples vs serum samples

n	slope	y-intercept	"r"	Range of Values
21	0.86	4.4	0.934	13 - 65 U/L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 2003

Thomas E. Worthy, Ph.D.
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Cholestech Corporation
3347 Investment Boulevard
Hayward, CA 94545

Re: k032027
Trade/Device Name: Cholestech LDX aspartate aminotransferase (AST) Test
Regulation Number: 21 CFR § 862.1100
Regulation Name: Aspartate amino transferase (AST/SGOT) Test System
Regulatory Class: II
Product Code: CIS
Dated: June 30, 2003
Received: July 1, 2003

Dear Dr. Worthy
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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number (if known): _____K032027_____

Device Name: Cholestech LDX aspartate aminotransferase (AST) Test

Indications for Use:

The Cholestech LDX aspartate aminotransferase (AST) test is for the in vitro quantitative determination of AST in whole blood or serum on the Cholestech LDX Analyzer.

AST measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis), and heart diseases.

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032027

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)