K991834

SEP 9 1999

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1. Submitter name, address, contact

Cholestech Corporation
3347 Investment Blvd.
Hayward, CA 94545-3808
(510) 293-8002
Fax: (510) 732-7227

Contact Person: Thomas Worthy

Date Prepared: 26 May 1999

2. Device name

Proprietary name: Cholestech L·D·X Alanine aminotransferase (ALT) Test

Common name: Colorimetric assay for the determination of alanine aminotransferase.

Classification name: Alanine aminotransferase (ALT/SGPT) test system

3. Predicate Device

The Cholestech L·D·X Alanine aminotransferase Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics Reflotron GPT (ALT) test.

4.Device Description

The Cholestech L·D·X Alanine Aminotransferase Test (ALT) combines an enzymatic methodology and a solid-phase technology to measure ALT in whole blood or serum. Blood from a fingerstick is collected into a lithium heparin coated capillary tube (venous whole blood serum is also acceptable) and dispensed into a L·D·X cassette. The cassette is then placed into the Cholestech L·D·X where a unique system separates the plasma from the blood cells. The plasma flows to both sides of the cassette and is transferred to the ALT reaction pad.

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510(k) Summary, Continued

4.Device Description, cont.

The Cholestech L•D•X Analyzer measures alanine aminotransferase by an enzymatic method based on the method formulation of Katsuyama et al. Alanine aminotransferase catalyzes the transfer of amino groups from L-Alanine and α-Ketoglutarate to pyruvate and glutamate. 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 ALT concentration of the sample. The resultant color in the reaction is measured by reflectance photometry.

L-Alanine + α -Ketoglutarate $\xrightarrow{\text{Alanine Aminotransferase}}$ Pyruvate + Glutamate

Pyruvate + Phosphate + O_2 + H_2O $\xrightarrow{\text{Pyruvate Oxidase}}$ Acetylphosphate + CO_2 + H_2O_2

Indicator + H_2O_2 $\xrightarrow{\text{Peroxidase}}$ Colored Blue Dye + H2O

A brown magnetic stripe on each cassette contains the calibration information required for the Cholestech L•D•X Analyzer to convert the reflectance reading to the ALT concentration in U/L at 37° C.

5. Intended use

The Cholestech L·D·X Alanine aminotransferase (ALT) Test is for the in vitro quantitative determination of alanine aminotransferase (ALT) in whole blood or serum on the Cholestech L·D·X Analyzer

6. Comparison to predicate device

The Cholestech L·D·X Alanine aminotransferase Test is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Roche Diagnostics Reflotron GPT (ALT) test (K864082).

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6. Comparison to predicate device, cont.

The following table compares the Cholestech L·D·X Alanine aminotransferase Test with the predicate device, Roche Diagnostics Reflotron GPT (ALT) test. Specific data on the performance of the test have been incorporated into the draft labeling in Section 5. Labeling for the predicate device is provided in Section 6.

Similarities:

- Intended Use: Colorimetric assay for the in vitro quantitative determination of alanine aminotransferase (glutamate pyruvate transaminase).
- Testing Sites: Clinical laboratories and point of care
- Test principle: Pyruvate oxidase and peroxidase catalyzed reactions

Differences:

Feature	L·D·X ALT	Reflotron GPT (ALT)
Instrument required	L·D·X Analyzer	Reflotron System
Assay Range	10 – 400 U/L	5 – 1200 U/L
Sample Type	Whole blood (capillary and venous) and serum	Whole blood (capillary and venous), serum and plasma

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510(k) Summary, Continued

6. Comparison to predicate device cont.

Performance Characteristics:

Feature	L·D·X ALT	Reflotron GPT (ALT)
Precision	NCCLS (modified): Within run (U/L) Level 1 / Level 2 / Serum Pool N: 20 / 20 / 20 Mean: 30.6 / 57.8 / 168.9 SD: 0.97 / 1.80 / 5.68 %CV: 3.2 / 3.1 / 3.4 Total (U/L): Level 1 / Level 2 / Serum Pool N: 20 / 20 / 20 Mean: 30.6 / 57.8 / 168.9 SD: 1.67 / 2.68 / 11.02 %CV: 5.4 / 4.6 / 6.5	(From Reflotron Package Insert) Within run (U/L) Level I / Level II / Pool N: 20 / 20 / 20 Mean: 51.0 / 110 / 166 SD: 1.01 / 3.0 / 5.1 %CV: 2.0 / 2.7 / 3.1 Day to Day Precision (U/L): Level I / Level II N: 15 / 15 Mean: 54.8 / 116.9 SD: 1.7 / 4.2 %CV: 3.1 / 3.6
Method Comparison	Vs Reflotron GPT (ALT): x = Capillary Whole Blood y = Capillary Whole Blood n = 24 y = 0.921x + 4.28; r = 0.932 x = Venous Whole Blood y = Venous Whole Blood n = 53 y = 0.916x + 0.269; r = 0.975 x = Serum y = Serum n = 52 y = 0.914x - .517; r = 0.971	Vs GPT (ALT) IFCC Method: x = Venous Heparin Blood y = Heparin Plasma n = 69 y = 1.02x – 3.6; r = 0.995 x = Serum y = Serum n = 36 y = 1.01x + 0.2; r = 0.999 x = Venous Heparin Plasma y = Venous Heparin Plasma n = 69 y = 1.04x – 3.3; r = 0.993 x = Capillary Heparin Blood y = Capillary Heparin Plasma n = 26 y = 0.969x + 4.7; r = 0.994

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6. Comparison to predicate device, (cont.)

Performance Characteristics, cont.:

Feature	L·D·X ALT	Reflotron GPT (ALT)
Interfering substances	No interference at:	No interference at:
Uric Acid	15 mg/dl	Not reported
Bilirubin	5 mg/dL	Not reported
Hematocrit	50%	55%
Lipemia	450 mg/dL triglycerides	400 mg/dL (cholesterol), 1700 mg/dL (triglycerides)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 9 1999

Thomas E. Worthy, Ph.D.
Director, Technical Affairs
Cholestech Corporation
3347 Investment Blvd.
Hayward, California 94545-3808

Re: K991834
Trade Name: Cholestech L·D·X Alanine Aminotransferase (ALT) Test
Regulatory Class: I
Product Code: CKD
Dated: July 23, 1999
Received: July 26, 1999

Dear Dr. Worthy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): N/A K991834

Device Name: Cholestech L·D·X Alanine aminotransferase Test (ALT)

Indications For Use:

The Cholestech L·D·X Alanine aminotransferase Test (ALT) is for the in vitro quantitative determination of alanine aminotransferase (ALT) in whole blood or serum on the Cholestech L·D·X Analyzer.

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

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991834

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)