

JUN 18 2004

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: K 040579

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

Submitter: Cholestech Corporation
3347 Investment Boulevard
Hayward, CA 94545
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Contact: Thomas E. Worthy, PhD.
Vice President, Research and Regulatory Affairs
Cholestech Corporation.

Summary Date: March 1, 2004

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

Name (trade): Cholestech LDX high sensitivity C-Reactive Protein (hs-CRP)
Name (usual): Immunoassay for the determination of C-Reactive Protein (CRP)
Classification: 21 CFR 866.5270, Class II, Product code DCK

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

LDX hs-CRP is substantially equivalent to the Dade Behring N *High Sensitivity* CRP assay on the BN100 (Dade Behring, Newark, DE). The LDX hs-CRP method is identical or similar to its predicate in terms of: intended use, measurement principle (immunoassay), undiluted sample 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 immunoassay and solid-phase technology to measure CRP. 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 hs-CRP 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 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 CRP concentration in mg/L.

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

Cholestech LDX high sensitivity C-Reactive Protein (hs-CRP) is an *in vitro* diagnostic test for the quantitative determination of CRP in whole blood or serum.

Measurement of CRP is useful as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

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

A summary table of the similarities and differences between the LDX hs-CRP and the predicate device follows.

Comparison Table:

Cholestech LDX hs-CRP vs Dade Behring BN100 *high sensitivity* CRP

Device Name	LDX hs-CRP (new device)	Dade Behring N <i>High Sensitivity</i> CRP Assay (K991385)
Indications for use	Cholestech LDX high sensitivity C-Reactive Protein (hs-CRP) test is an <i>in vitro</i> diagnostic test for the quantitative determination of C-reactive protein (CRP) in whole blood or serum. Measurement of CRP is useful as an aid in the detection and evaluation of infection, tissue	N <i>High Sensitivity</i> CRP is an <i>in vitro</i> diagnostic assay intended for the quantitative determination of C-reactive protein (CRP) in human serum and heparin- and EDTA- plasma by means of particle enhanced immunonephelometry using BN™ Systems. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement

Device Name	LDX hs-CRP (new device)	Dade Behring N <i>High Sensitivity</i> CRP Assay (K991385)
	injury, inflammatory disorders and associated diseases.	of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases
Instrument Required	Cholestech LDX Analyzer	Dade Behring BN-100 Nephelometer
Technology	Lateral flow immunoassay utilizing colloidal gold particles coated with monoclonal antibodies detected by reflectance spectrophotometry.	Agglutination of polystyrene particle coated with monoclonal antibodies detected by nephelometry
Assay Range	0.2 to 10 mg/L	0.175 to 11 mg/L up to 1100 mg/dL with sample dilution
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 N CRP Standard SY; under typical operating conditions, the HS-CRP reagents must be calibrated every 4 weeks, and also with certain parts replacement or maintenance procedures.
Testing Environment	Professional-Use, point-of-care	Professional-Use, conventional laboratory

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

- Assay range: 0.2– 10 mg/L
- Hematocrit tolerance: 30-55%
- Interference testing: less than 10% interference when challenged by evaluated levels of endogenous substances
- Precision: 2 levels of Controls (Low- ~1.2 mg/L CRP, and High- ~2.9 mg/L CRP) 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 14.3%, and 11.5% from the testing of the High Control. When the same testing protocol was performed with a serum sample at 6.5 mg/L, the %CV was 11.4%.

- Accuracy: The LDX hs-CRP test was compared to the Dade Behring N *high sensitivity* CRP test with 70 matched serum samples. Additionally, results obtained from testing 76 whole blood samples (both venous and fingerstick) on the LDX were compared to the serum results obtained on the Dade Behring N *high sensitivity* CRP. (Dade Behring N *high sensitivity* CRP on x-axis).

LDX hs-CRP vs Dade Behring N *high sensitivity* CRP

	n	slope	y-intercept	“r”	Range of Values
Serum	70	1.01	0.22	0.975	0.20 – 7.18 mg/L
Whole Blood	76	1.06	0.07	0.976	0.20 – 7.18 mg/L
Fingersticks	76	1.08	-0.02	0.981	0.20 – 8.65 mg/L



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 2004

Thomas E. Worthy, Ph.D.
Vice President, Development and Regulatory Affairs
Cholestech Corp.
3347 Investment Blvd.
Hayward, CA 94545

Re: k040579
Trade/Device Name: Cholestech LDX High-Sensitivity C-Reactive Protein (HS-CRP)
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCK
Dated: May 19, 2004
Received: May 20, 2004

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.

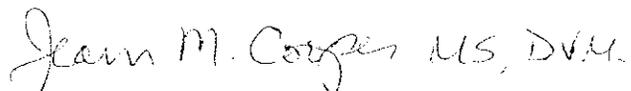
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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,



Jean M. Cooper, MS, D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040579

Device Name: Cholestech LDX High-Sensitivity C-Reactive Protein (HS-CRP)

Indications For Use:

Cholestech LDX high sensitivity C-Reactive Protein (hs-CRP) is an *in vitro* diagnostic test for the quantitative determination C-reactive protein in whole blood or serum. Measurement of CRP is useful as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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