

K981345

Lifestream Technologies, Inc.  
Cholesteron™ Pro II Cholesterol Test  
Response Cycle #1 for K981345

OCT 1 1998

**SECTION 10**  
**510(K) SUMMARY**  
**(REVISED)**



## 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: K981345.

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

Submitter: Lifestream Technologies, Inc.  
510 Clearwater Loop, Suite 101  
Post Falls, ID 83854  
phone: (208) 457-9409  
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Contact: Jackson B. Connolly  
Director, Product Development  
Lifestream Diagnostics, Inc.  
phone: (208) 457-9409

Summary Date: April 13, 1998

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

Name (trade): Cholestron™ Pro II Cholesterol Test

Name (usual): total cholesterol test system

Classification: 21 CFR 862.1175, Class I, CHH

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

Cholestron™ Pro II Cholesterol Test (Cholestron) is substantially equivalent to the Accu-Chek® InstantPlus™ Cholesterol Test (Boehringer-Mannheim Diagnostics, Indianapolis, IN; also known as Accutrend GC Test). Cholestron and Accu-Chek share the same intended use, methodology and technology, testing matrix, reportable range, and risk to the patient.

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

The Cholestron system consists of a photometer with a display assembly keypad, and single-use, disposable reagent strips. Fingerstick whole blood is applied directly to the device, and cholesterol results are available in approximately three minutes.

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

The Cholestron™ Pro II Cholesterol Test is a professional-use, point-of-care in vitro diagnostic device for the measurement of total cholesterol in fingerstick whole blood samples. Total cholesterol measurements aid in the detection of persons who may be at risk for coronary heart disease, and aid in the management of patients undergoing therapy with lipid lowering drugs.

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

A summary table of the similarities and differences between Cholestron and the predicate device (Accu-Chek) follows.

### Similarities Between Cholestron and Accu-Chek

CHARACTERISTIC	CHOLESTRON	Accu-Chek
<b>Intended Use</b>	total cholesterol measurement to aid in the diagnosis and management of coronary heart disease	total cholesterol measurement to aid in the diagnosis and management of coronary heart disease
<b>Analyte Measured</b>	total cholesterol	total cholesterol
<b>Methodology/Technology</b>	<p>Enzymatic: cholesterol esterase and cholesterol oxidase (Trinder Reaction)</p> <p>Cholesterol esterase reacts with lipoproteins in the sample to split the cholesterol ester into cholesterol and fatty acid. Cholesterol is oxidized to 4-cholesten-3-one and H<sub>2</sub>O<sub>2</sub> in the presence of cholesterol oxidase. Hydrogen peroxidase reacts with a reducing agent to produce a blue color that is measured photometrically.</p>	<p>Enzymatic: cholesterol esterase and cholesterol oxidase (Trinder Reaction)</p> <p>Cholesterol esterase reacts with lipoproteins in the sample to split the cholesterol ester into cholesterol and fatty acid. Cholesterol is oxidized to 4-cholesten-3-one and H<sub>2</sub>O<sub>2</sub> in the presence of cholesterol oxidase. Hydrogen peroxidase reacts with a reducing agent to produce a blue color that is measured photometrically.</p>
<b>Testing Matrix</b>	fingerstick whole blood	fingerstick whole blood
<b>Reportable Range</b>	150-300 mg/dL	150-300 mg/dL
<b>Risk to Patient</b>	minimal, not a sole discriminate; total cholesterol results are interpreted along with medical histories and other biochemical markers	minimal, not a sole discriminate; total cholesterol results are interpreted along with medical histories and other biochemical markers

**Differences Between Cholestroton and Accutrend**

<b>CHARACTERISTIC</b>	<b>CHOLESTRON</b>	<b>ACCUTREND K944458 (cholesterol portion)</b>
<b>Safety Feature for Correct Reagent Strip Usage</b>	includes external keypad that requires correct entry of reagent strip lot information	no such feature
<b>User Interface</b>	16-key	4-key
<b>Battery Power</b>	1 9-volt	3 AAA
<b>Electronics</b>	Diagnostic + Memory + Display Conversion + Code # Correlation to Lot # (safety) + Cardiac Risk Assessment	Diagnostic + Memory

Brief Discussion of Nonclinical Data (21 CFR 807.92(b)(1))

Laboratory tests were conducted to assess the effects of potential interferents on the cholesterol results; both biological and therapeutic compounds were evaluated. The results appear below.

**INTERFERENCE TESTING WITH BIOLOGICAL COMPOUNDS**

<b>Potential Interferent</b>	<b>Level of Interference</b>
Bilirubin	no interference in samples containing up to 10 mg/dL
Hemoglobin	hemolyzed samples (as would be seen in cases of excessive squeezing at the puncture site) should be avoided
High Hematocrit	cholesterol values were not affected when hematocrit levels ranged from 30% to 55%
Triglycerides	no interference in samples containing up to 400 mg/dL
Uric Acid	no interference in samples containing up to 9 mg/dL
Excessive Squeezing of Puncture Site	excessive squeezing and milking of the puncture site may produce erroneous results

### Therapeutic Compounds

Specificity testing was performed with common therapeutic compounds. The following compounds, when present in pathological concentrations, were found to possibly alter cholesterol results.

Acetaminophen  
Ascorbic Acid  
Dopamine  
Gentisic Acid  
Methyldopa

### Brief Discussion of Clinical Data (21 CFR 807.92 (b)(2))

Studies were performed to evaluate accuracy and precision. Accuracy was evaluated by two studies of 62 subjects each, where results from testing with the Cholesteron on fingerstick whole blood samples by each of two operators were compared to venous serum samples assayed by the reference Abell-Kendall (A-K) method. Precision was evaluated in both serum and whole matrices with two levels of cholesterol samples. Serum samples (commercial controls) were assayed in multiple "runs" over several days, and whole blood samples were assayed in single runs on a single day.

### CHOLESTRON ACCURACY STATISTICS

Comparison	n =	r =	Slope	y-intercept	Bias at 200 mg/dL (% bias)	Bias at 240 mg/dL (% bias)
Operator #1 vs A-K	57*	0.95	0.855	32	203 (1.50%)	237 (-1.25%)
Operator #2 vs A-K	62**	0.94	0.840	37	205 (2.50%)	239 (-0.42%)
Operator #3 vs A-K	62	0.94	0.858	32	204 (2.00%)	238 (-0.83%)
Operator #4 vs A-K	62	0.93	0.882	28	204 (2.00%)	240 (-zero)

\* 5 Cholesteron values out of range

\*\*1 Cholesteron value out of range

The data demonstrate all comparative biases were within 3%, as specified by National Cholesterol Education Program (NCEP) guidelines. Each operator obtained Cholesteron results that compared closely with the A-K results, and the Cholesteron meets NCEP's guidelines for accuracy.

### SERUM PRECISION

A two-level commercial control set was assayed six times a day (three replicates in the morning, and three replicates in the afternoon) over five days for a total of 30 replicates for each level. The controls were label-assigned at mean values of 180 mg/dL ("Low", range 154-207 mg/dL) and 256 mg/dL ("High", range 221-292 mg/dL), and testing was performed via the pipetting of 25 $\mu$ L of sample onto each of two Cholesteron devices.

#### SUMMARIZED SERUM PRECISION DATA- LOW CONTROL

DAY	N =	MEAN	STANDARD DEVIATION	PERCENT COEFFICIENT OF VARIATION
1	6	184.7	2.58	1.40
2	6	186.3	3.27	1.75
3	6	183.7	2.94	1.60
4	6	186.3	2.50	1.34
5	6	181.2	1.94	1.07
Weekly	30	184.4	3.17	1.72

#### SUMMARIZED SERUM PRECISION DATA- HIGH CONTROL

DAY	N =	MEAN	STANDARD DEVIATION	PERCENT COEFFICIENT OF VARIATION
1	6	228.5	6.38	2.79
2	6	233.2	4.26	1.83
3	6	233.0	7.38	3.17
4	6	234.2	8.73	3.73
5	6	225.8	3.31	1.47
Weekly	30	230.9	6.73	2.91

Cholesteron's within-day imprecision ranged from 1.07 %CV to 1.75 %CV with the Low control, and from 1.47 %CV to 3.73 %CV with the High Control. The between-day (or total) imprecision was 1.72 %CV for the Low Control, and 2.91% CV for the High Control. Testing of the serum controls demonstrated Cholesteron meets the NCEP guidelines for precision with %CVs within 3%.

### WHOLE BLOOD PRECISION

Whole blood precision was evaluated by repeat testing of two levels of venous heparinized whole blood; the whole blood samples were targeted at 200 mg/dL and 240 mg/dL. Whole blood precision was included in the clinical trial as this is the relevant matrix for the Cholestron. Testing was performed via the pipetting of 25 $\mu$ L of sample onto the devices.

#### SUMMARIZED WHOLE BLOOD PRECISION DATA

LEVEL ID	N =	MEAN	STANDARD DEVIATION	PERCENT COEFFICIENT OF VARIATION
LOW	30	179.4	2.50	1.39
HIGH	30	228.1	5.43	2.38

The data demonstrated %CVs of 1.39% ("Low"), and 2.38% ("High"). The whole blood precision testing corroborated the serum precision testing, and confirms Cholestron meets the NCEP guidelines for precision with %CVs within 3%.

#### Performance Data - Conclusions (21 CFR 807.92 (b)(3))

Studies were conducted to evaluate Cholestron's accuracy and precision. Accuracy was assessed by paired testing of 62 whole blood/serum samples in two separate evaluations, and precision was assessed by repeated analyses of serum controls and whole blood samples.

The data demonstrated Cholestron meets the NCEP guidelines for accuracy and precision, with estimated biases within 3% of the reference method, and with percent coefficients of variation within 3%.



OCT 1 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Lifestream Technologies, Inc.  
• C/O Erika B. Ammirati, R.A.C. MT(ASCP)  
Ammirati Regulatory Consulting  
575 Shirlynn Court  
Los Altos, California 94022

Re: K981345  
Cholestrol™ Pro II Cholesterol Test  
Regulatory Class: I  
Product Code: CHH  
Dated: August 26, 1998  
Received: August 28, 1998

Dear Ms. Ammirati:

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 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 (Pre-market 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 pre-market 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/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

### SECTION 3 INTENDED USE/INDICATIONS FOR USE

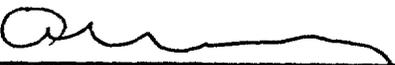
#### INTENDED USE

The Cholestron™ Pro II Cholesterol Test (Cholestron) is a professional-use, point-of-care in vitro diagnostic device for the measurement of total cholesterol in fingerstick whole blood samples.

#### INDICATIONS FOR USE

Total cholesterol measurements aid in the detection of persons who may be at risk for coronary heart disease, and aid in the management of patients undergoing therapy with lipid lowering drugs.

The measurement range for the Cholestron is 150 - 300 mg/dL.

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K981345