

AUG 3 1998

K981181

**510(k) SUMMARY**

**ACTIMED LABORATORIES, INC.  
ENA-C-T™ Total Cholesterol Test  
Physicians Directed Use**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

Susan McGeehan  
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ActiMed Laboratories, Inc.  
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Burlington, NJ 08016  
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Contact Person: same as above

Date Prepared: March 27, 1998

**Name of Device and Name/Address of Sponsor**

*ENA-C-T™ Total Cholesterol Test*

ActiMed Laboratories, Inc.  
5 Terri Lane  
Burlington, NJ 08016

**Classification Name**

Cholesterol (total) test system

**Predicate Device**

ActiMed Laboratories, Inc., *ENA-C-T™ Total Cholesterol Test (POL)*  
(K960377) and ChemTrak AccuMeter® Cholesterol Test (K905405).

K981181

## Intended Use and Indications for Use

The ActiMed *ENA-C-T™* Total Cholesterol Test is a non-instrumented, enzymatic assay intended for the *in vitro* quantitative determination of total cholesterol in fingerstick whole blood. It is indicated for physician directed use (PDU) by the patient for screening and monitoring cholesterol.

In a PDU **monitoring** application, the patient's physician (or other medical professional under the direction of a physician) initially trains the patient to use the test properly and provides information on the proper interpretation of results and limitations of the test. With the physician directed indication for use, patients on cholesterol lowering therapy can test their own total cholesterol at home and provide the results to their physician or other healthcare organization which works with the physician to maintain compliance on the therapy.

In a PDU **screening** application, a physician (or other medical professional under the direction of a physician) initially trains a group of individuals to use the test properly and provides information on the proper interpretation of results and limitations of the test. The physician directed use version of the *ENA-C-T™* Total Cholesterol Test kits are then distributed to the group of individuals who can use the test at home and then communicate their results to the physician or healthcare organization.

## Technological Characteristics and Substantial Equivalence

The *ENA-C-T™* Total Cholesterol Test is based on stable, dry chemistry reagents embedded in a flow device with a factory calibrated scale. The device provides a direct visual read-out of test results. It has built-in controls to indicate that a sufficient volume of whole blood has been added as sample, to verify that the reagents are functioning, and to confirm when the test has been completed. The test device is self-actuating, requiring neither timing nor handling between addition of the sample and reading the result.

The *ENA-C-T™* Total Cholesterol Test - Physicians Directed Use (PDU) is substantially equivalent to the *ENA-C-T™* Total Cholesterol Test (POL) in terms of intended use, design, materials, operational features, and performance. Both devices are based upon an enzymatic reaction that occurs when whole blood is added to dry chemistry reagents embedded in a flow device. Both devices are standardized to the National Reference System for Cholesterol (NRS/CHOL). Results from both devices are read visually within approximately 15-20 minutes of addition of sample to the device. For both

K 981181

versions of the *ENA-C-T™* Total Cholesterol Test, results in mg/dL are read directly from a lot-specific, factory-calibrated scale printed on the device.

Both the *ENA-C-T™* Total Cholesterol Test (PDU) and the *ENA-C-T™* Total Cholesterol Test (POL) have built-in controls. Both versions of the *ENA-C-T™* Total Cholesterol test have controls to indicate that a sufficient volume of whole blood has been added as sample, to verify that the reagents are functioning, and to confirm when the test has been completed.

Performance characteristics generated during analytical and clinical studies on the *ENA-C-T™* Total Cholesterol Test (PDU) are comparable to those generated in the same study for the *ENA-C-T™* Total Cholesterol Test (POL). The linear range of both versions of the *ENA-C-T™* Total Cholesterol Test is 120 mg/dL to 360 mg/dL. The recovery of cholesterol in the presence of potentially interfering substances was determined for the *ENA-C-T™* device. No interference was found in samples containing up to 10 mg/dL ascorbic acid, 11 mg/dL uric acid, 250 mg/dL of hemoglobin, 850 mg/dL of triglycerides, or 20 mg/dL bilirubin. Acetaminophen interferes at a level of 1 mg/dL. The test is affected by high concentrations of ascorbic acid.

Precision results for these two visually read tests are comparable, with percent coefficients of variation generally less than 6.9% for paired fingerstick whole blood samples.

In clinical studies at three POL sites, *ENA-C-T™* Total Cholesterol Test (PDU), *ENA-C-T™* Total Cholesterol Test (POL), and CRMLN results were generated on 136 paired fingerstick whole blood and venous samples. Correlation's between the *ENA-C-T™* Total Cholesterol Test (PDU) and the CRMLN methods and between the *ENA-C-T™* Total Cholesterol Test (PDU) and the *ENA-C-T™* Total Cholesterol Test (POL) were acceptable. Thus, the *ENA-C-T™* Total Cholesterol Test (PDU) is substantially equivalent to the *ENA-C-T™* Total Cholesterol Test (POL) in terms of performance characteristics, as well as intended use, design, materials, and operational features.

## **Analytical and Clinical Testing**

### Linear Range

Results from NCCLS Linearity Protocol testing and from testing 40 normal and abnormal clinical samples demonstrated that the linear range of the *ENA-C-T™* Total Cholesterol Test is 120 mg/dL to 360 mg/dL.

K981181

### Interfering Substances

Studies of the recovery of cholesterol in the presence of potentially interfering substances were carried out. No interference was found in samples containing up to 10 mg/dL ascorbic acid, 11 mg/dL uric acid, 250 mg/dL of hemoglobin, 850 mg/dL of triglycerides, or 20 mg/dL bilirubin. Acetaminophen interferes at a level of 1 mg/dL.

### Precision

The precision of the devices has been established by using data for the *ENA-C-T™* device from the clinical studies. Precision was determined by obtaining the differences between self test/self read and professional test/professional read devices for each subject at each site. The CVs were 5.2%, 6.7%, and 8.8% for Site 1, 2, and 3 respectively, with an average CV for all sites of 6.9%. These results demonstrate that the visually read *ENA-C-T™* Total Cholesterol Test was reproducible in the hands of patients trained in the use of the device.

### Clinical Studies

A total of 136 paired fingerstick whole blood and venous samples were tested during clinical studies at three POL sites. Fingerstick whole blood samples were assayed at the sites by the *ENA-C-T™* Total Cholesterol Test and venous samples were assayed at a Cholesterol Reference Method Network Laboratory (CRMLN) by the Abell-Kendall serum reference method or enzymatic method. For the comparison between the *ENA-C-T™* Total Cholesterol Test (PDU) and the CRMLN method, the least squares regression equation for all sites was  $y = 1.018x + 2.13$ , with a correlation coefficient of  $r = 0.917$ . Bias at 200 mg/dL and at 240 mg/dL was 2.86% and 2.69%, respectively. For the comparison between the *ENA-C-T™* Total Cholesterol Test (PDU) and the *ENA-C-T™* Total Cholesterol Test (POL), the least squares regression equation for all sites was  $y = 0.931x + 13.8$ , with a correlation coefficient of  $r = 0.899$ .

Precision studies conducted at three POL sites have demonstrated that the visually read *ENA-C-T™* Total Cholesterol Test is reproducible, with an average CV of 6.9% for paired fingerstick whole blood samples from a total of 136 subjects. Clinical studies compared the *ENA-C-T™* Total Cholesterol Test (PDU) to the CRMLN serum reference method and the *ENA-C-T™* Total Cholesterol Test (PDU) to the *ENA-C-T™* Total Cholesterol Test (POL) on samples from 136 patients. Bias of the *ENA-C-T™* device (PDU), compared to the CRMLN serum reference method was 2.86% at the 200 mg/dL level and

K 981181

2.69% at the 240 mg/dL for the combined sites. These figures are well within the recommendation of the Laboratory Standardization Panel (LSP) on Blood Cholesterol Measurement that bias not exceed 3%. Correlations between the *ENA-C-T™* device (PDU) and the CRMLN Method and between the *ENA-C-T™* device (PDU) and the *ENA-C-T™* device (POL) were within 10%. Thus, the *ENA-C-T™* Total Cholesterol Test (PDU) has demonstrated acceptable precision, bias and accuracy, and has been shown to be substantially equivalent to the *ENA-C-T™* Total Cholesterol Test (POL).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

AUG 3 1998

Susan McGeehan  
• Manager - Quality Assurance  
ActiMed Laboratories, Inc.  
5 Terri Lane  
Burlington, New Jersey 08016

Re: K981181  
ENA·C·T™ Total Cholesterol Test Model F 20000, (Physician  
Directed Use)  
Regulatory Class: I  
Product Code: CHH  
Dated: March 27, 1998  
Received: April 1, 1998

Dear Ms. McGeehan:

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 (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.

Page 2

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 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): K981181

Device Name: ENA-C-T™ Total Cholesterol Test (Physician-Directed Use)

**Indications for Use:**

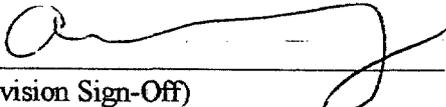
The ActiMed *ENA-C-T™* Total Cholesterol Test is a non-instrumented, enzymatic assay intended for the *in vitro* quantitative determination of total cholesterol in fingerstick whole blood. It is indicated for physician directed use (PDU) by the patient for screening and monitoring cholesterol.

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

Concurrence of CDRH, Office of Device Evaluation

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K981181

Prescription Use   
Per 21 CFR 801.109

OR

Over-The Counter Use