

SEP 21 1998

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 982767

1. Submitter's Name/Contact Person

Melissa Saner/Technical Marketing Manager

Address

Raichem Division of Hemagen Diagnostics, Inc. # 2022395
Formerly: Reagents Applications, Inc.
8225 Mercury Court
San Diego, CA 92129
Phone: 619-569-8009 extension 111
Fax: 619-569-6208
Email: msaner@raichem.com

Date Prepared

August 4, 1998

2. Device Name

Trade Name:	Raichem HDL-Cholesterol Direct Reagent
Common Name:	High density (HDL) cholesterol test
Classification Name:	Lipoprotein test system
Device Classification:	I
Regulation Number:	21 CFR 862.1475
Panel:	Chemistry (75)
Product Code:	LBS

Trade Name:	HDL-Cholesterol Calibrator
Common Name:	HDL-Cholesterol Calibrator
Classification Name:	Calibrator, Primary
Device Classification:	II
Regulation Number:	21 CFR 862.1150
Panel:	Chemistry (75)
Product Code:	JIS

3. Predicate Device

CDC Designated Comparison Method: Cholesterol Reference Method Laboratory Network

Raichem HDL-Cholesterol Reagent: 510(k) Docket No. K830207A

Boehringer Mannheim Direct HDL-Cholesterol: 510(k) Docket No. K963213

Boehringer Mannheim C.f.a.s. HDL-C (Calibrator): 510(k) Docket No. K963213

Raichem Serum Calibrator (Ortho Automated Reference Serum Assayed -

Marketed by Chiron Diagnostics): No 510(k) Docket Number Assigned (Pre Medical Device Amendments of 1976) (Medical Device Listing Document No. A 268140)

4. Description of Device

The Raichem HDL-Cholesterol Direct test is based upon two sets of reaction sequences. In the first set of reactions Chylomicrons, VLDL and LDL selectively react with cholesterol esterase and are then eliminated from the reaction scheme. The addition of the second reagent causes the reaction of HDL-Cholesterol with cholesterol esterase and the subsequent production of color. The resultant increase in absorbance is directly proportional to the concentration of HDL-Cholesterol in the sample.

The Raichem HDL-Cholesterol Calibrator is a serum calibrator used for the calibration of the Raichem HDL-Cholesterol Direct assay.

5. Intended Use of Device

The Raichem HDL-Cholesterol Direct Reagent is intended for the quantitative determination of HDL-Cholesterol in serum or plasma.

The Raichem HDL-Cholesterol Calibrator is intended to be used for the calibration of the Raichem HDL-Cholesterol Direct assay.

6. Substantial Equivalence

A. Technological Characteristics

Proposed Device

1. The Raichem HDL-Cholesterol Reagent involves the direct selective reaction of HDL-Cholesterol utilizing surfactants and $MgCl_2$ in a specific buffered environment.
2. The Raichem HDL-Cholesterol Calibrator is a serum calibrator used for the calibration of the Raichem HDL-Cholesterol Direct assay.

Predicate Device

1. The Designated Comparison Method is performed by a laboratory that is part of the Cholesterol Reference Method Laboratory Network. This method is standardized to the CDC reference method for HDL-Cholesterol.
2. The Raichem HDL-Cholesterol Reagent involves the precipitation of VLDL and LDL utilizing dextran sulfate (500,000 MW) and magnesium sulfate.
3. The Boehringer Mannheim Direct HDL-Cholesterol is a homogenous assay involving the selective reaction of HDL-Cholesterol utilizing PEG and sulfated cyclodextrin.
4. The Raichem Serum Calibrator (Ortho Automated Reference Serum) is a device purchased from Chiron Diagnostics by Raichem. This device is a serum calibrator used for the calibration of clinical chemistry assays.

B. Performance Data

Precision

Precision studies were performed in 48 runs over a period of 24 days following the NCCLS EP5-T2 Tentative Guideline.

Mean (mg/dL)	Total		Within Run	
	SD	CV %	SD	CV %
33.1	0.89	2.7	0.26	0.8
51.21	1.35	2.6	0.32	0.6

Standardization of the Calibrator

The value for the calibrator is established by ultracentrifugation. It is traceable to the National Institute of Standards Standard Reference Material (1951a). The procedures used to assign the value to this calibrator material meet the requirements of the "HDL Cholesterol Method Evaluation Protocol for Manufacturers" of the U.S. National Reference System for Cholesterol, CRMLN (Cholesterol Reference Method Laboratory Network), August 1995.

Lower Detection Limit

The lower detection limit for the proposed device was determined to be 1 mg/dL.

Linearity

1 to 150 mg/dL

Comparison Testing

1. Comparison of Raichem HDL-Cholesterol Direct Reagent (y) with the CDC HDL-Cholesterol designated comparison method (x). Testing was performed in accordance with NCCLS EP9-A Approved Guideline. The Raichem HDL-Cholesterol Direct assay was performed using the Raichem Serum Calibrator (Ortho Automated Reference Serum) on the Hitachi 717.

Number of sample pairs (n):	47
Range of results (mg/dL):	24 – 70
Correlation Coefficient:	0.987
Regression Equation:	$y = 0.9488x + 2.0$

2. Comparison of Raichem HDL-Cholesterol Direct Reagent (y) with Raichem HDL-Cholesterol Reagent (500,000 MW dextran sulfate) (x), following the NCCLS EP9-A Approved Guideline.

Number of sample pairs (n):	48
Range of results (mg/dL):	23.0 – 77.1
Correlation Coefficient:	0.988
Regression Equation:	$y = 1.011x + 0.192$



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Melissa Saner
. Technical Marketing Manager
Raichem
8225 Mercury Court
San Diego, California 92111-1203

Re: K982767
HDL-Cholesterol Direct Reagent and Calibrator
Regulatory Class: I & II
Product Code: JIX, LBS
Dated: August 4, 1998
Received: August 6, 1998

Dear Ms. Saner:

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

Device Name: HDL-Cholesterol Calibrator

Indication(s) For Use

This calibrator is intended to be used for the calibration of the Raichem HDL-Cholesterol Direct assay.

Device Name: HDL-Cholesterol Direct Reagent

Indication(s) For Use

This reagent is intended to be used for the quantitative determination of HDL-Cholesterol in human serum or plasma.

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use _____


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982767