JUL 13 1999

K991733

510(k) PREMARKET NOTIFICATION
ACE® LDL-C Reagent

SUMMARY OF SAFETY AND EFFECTIVENESS

In lieu of a 510(k) statement under 513(i) of the Act, this Summary of Safety and Effectiveness is provided as a 510(k) summary for disclosure to any other persons/companies without specific written authorization from Schiapparelli Biosystems, Inc.

Submitter
Schiapparelli Biosystems, Inc.
368 Passaic Avenue
Fairfield, NJ 07004
Phone: (973) 882-8630

Contact Person
Steven Dalessio
Manager, Quality Assurance/Regulatory Affairs
Phone: (973) 882-8630

Device Names

Proprietary Name:	ACE® LDL-C Reagent LDL-C Calibrator LDL-C Controls
Common Name:	Homogeneous assay for low density lipoprotein cholesterol
Classification Name:	Low density lipoprotein cholesterol test Calibrator, Primary Low density lipoprotein cholesterol control
Predicate Device:	Genzyme N-geneous® LDL Cholesterol Reagent [510(k) Number K971573] Genzyme N-geneous® LDL Cholesterol Calibrator Genzyme LDL Control Set

Device Description

The ACE® LDL-C Reagent contains two reagents. An aliquot of serum is added to the first reagent, which contains a unique detergent that selectively solubilizes the non LDL lipoproteins. Enzymes also present in the first reagent consume the cholesterol in a non color forming reaction. The second reagent contains another detergent that releases the remaining LDL lipoproteins. The enzyme reaction with LDL cholesterol, in the presence of a chromogenic coupler, produces color that is directly proportional to the amount of LDL cholesterol in the sample.

Intended Use of the Device
ACE® LDL-C Reagent is intended for use in the quantitative determination of low density lipoprotein cholesterol in human serum.

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COMPARATIVE FEATURES OF PREDICATE AND PROPOSED DEVICES

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
Trade Name	Genzyme N-geneous® LDL Cholesterol Reagent	ACE® LDL-C Reagent
Reference No.	K971573	TBD
Analyte	LDL cholesterol	LDL cholesterol
Intended Use	Quantitative determination of LDL cholesterol	Quantitative determination of LDL cholesterol
Methodology	Homogeneous, Direct	Homogeneous, Direct
Reagents **Reagent 1** **Volume** **Reagent 2** **Volume**	 Liquid; Detergent, Enzymes 300 µL Liquid; Detergent, Chromogenic coupler 100 µL	 Liquid; Detergent, Enzymes 300 µL Liquid; Detergent, Chromogenic coupler 100 µL
Specimen **Type** **Volume**	 Serum and plasma 3 µL	 Serum 3 µL
Assay System **Reagent 1 + Sample** **Reagent 2** **Temperature**	 Incubate 300 sec and Read Read at 300 sec 37 °C	 Incubate 300 sec and Read Read at 300 sec 37 °C
Detection Method **Type** **Wavelength, nm**	 Spectrophotometric Bichromatic: 546/660	 Spectrophotometric Bichromatic: 544/692

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PERFORMANCE ASSESSMENT

Non-clinical test results submitted in the premarket notification include within-run and between-run precision and method correlation. Following is a data summary.

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
Performance Summary		
Assay Range	6.6 mg/dL to 992 mg/dL	3 mg/dL to 800 mg/dL
Precision		
Within Run	≤ 0.73 %CV	≤ 2.6 %CV
Between Run	≤ 2.27 %CV	≤ 3.2 %CV
Correlation vs	**Reference method (Ultracentrifugation)**	**Hitachi 911**
Slope	0.95	1.111
Intercept	+3.02	-15.5
r	0.96	0.9747
n	54	70
Correlation vs	**Immunoseparation method**	**Friedewald calculation**
Slope	0.94	1.09
Intercept	+4.46	-17.8
r	0.97	0.9728
n	92	66

Based on these data, the Schiapparelli Biosystems ACE® LDL-C Reagent is substantially equivalent to the predicate device Genzyme N-geneous® LDL Cholesterol Reagent. On this basis, the reagent is determined to be safe and effective for its intended use. Performance details are included in the reagent product labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 1999

Mr. Steven Dalessio
Manager, Quality Assurance/Regulatory Affairs
Schiapparelli Biosystems, Inc.
368 Passaic Avenue
Fairfield, New Jersey 07004

Re: K991733
Trade Name: ACE® LDL-C Reagent
Regulatory Class: I reserved (Product codes: MRR, JJX)
II (Product code: JIS)
Dated: May 20, 1999
Received: May 21, 1999

Dear Mr. Dalessio:

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): K991733

Device Name: ACE® LDL-C Reagent

Indications For Use:

ACE® LDL-C Reagent is intended for the quantitative determination of LDL cholesterol in serum using the ACE® clinical chemistry system.

LDL-C Calibrator is intended for the calibration of the ACE® LDL-C Assay.

LDL-C Controls are intended to monitor the performance of the ACE® LDL-C Assay.

The measurement of LDL cholesterol is a factor in the pathogenesis of atherosclerosis and coronary artery disease.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991733

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)