

510(k) PREMARKET NOTIFICATION
Summary of Safety and Effectiveness
ACE™ HDL-C Reagent

K971526

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: (201) 882-8630

MAY 21 1997

Contact Person

Steve Dalessio
Manager, Quality Assurance and Regulatory Affairs
Phone: (201) 882-8630

Device Names

Proprietary Name: ACE™ HDL-C Reagent
Common Name: Homogeneous assay for high density lipoprotein cholesterol
Classification Name: High density lipoprotein cholesterol test

Predicate Device

Genzyme Corporation's - N-geneous™ HDL Cholesterol Reagent [510(k) Number K962186]

Device Description

An aliquot of serum is added to the first reagent which contains a mixture of polymers and polyanions that bind to the surface of low-density lipoproteins (LDL), very low-density lipoproteins (VLDL) and chylomicrons. These complexed lipoproteins are stabilized, even in the presence of detergent, which is added as part of the second reagent, together with cholesterol enzymes. HDL particles are not stabilized by the polymers and polyanions and become solubilized by the detergent. As a result, only the HDL cholesterol is subject to measurement.

Intended Use of the Device

ACE™ HDL-C Reagent is intended for use in the quantitative determination of HDL cholesterol in human serum.

**Summary of Safety and Effectiveness
ACE™ HDL-C Reagent**

COMPARATIVE FEATURES OF PREDICATE AND PROPOSED DEVICE

PARAMETER	PREDICATE DEVICE	PROPOSED DEVICE
Trade Name	N-geneous™ HDL Cholesterol	ACE™ HDL-C Reagent
Reference No.	K962186	TBD
Analyte	HDL Cholesterol	HDL Cholesterol
Intended Use	Quantitative determination of HDL Cholesterol	Quantitative determination of HDL Cholesterol
Methodology	Homogeneous; Direct	Homogeneous; Direct
<i>Reagents</i>		
Reagent 1 Volume	Liquid; Polyanion, Polymer 300 uL	Liquid; Polyanion, Polymer 300 uL
Reagent 2 (Diluent)	Liquid; Detergent	Liquid; Detergent
Reagent 3 (Recon with Rgt 2) Volume	Lyophilized; Enzymes 100 uL	Lyophilized; Enzymes 100 uL
<i>Specimen</i>		
Type	Serum and Plasma	Serum
Volume	3 uL	3 uL
<i>Assay System</i>		
Reagent 1 + sample	Incubate 300s	Incubate 300s
Reagent 3	Incubate 24 - 300s	Incubate 300s
Temperature	37C	37C
<i>Detection Method</i>		
Type	Spectrophotometric	Spectrophotometric
Wavelength, nm	Bichromatic: 546/660	Bichromatic: 544/692

HHDL510K.WPS

**Summary of Safety and Effectiveness
ACE™ HDL-C Reagent**

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		<i>125</i>
Assay Range	2 mg/dL to 200 mg/dL	2 mg/dL to 100 mg/dL
Precision		
Within Run	< 1.5 %CV	< 2.7 % CV
Between Run	< 3.8 %CV	< 4.6 %CV
Correlation vs CDC Ref		
Slope	1.01	1.014
Intercept	-3.39	0.13
r	0.96	0.986
Correlation vs	Phosphotungstic Acid Ppt	Dextran Sulfate Ppt
Slope	0.81	0.991
Intercept	7.82	0.55
r	0.96	0.976

Based on these data , the Schiapparelli Biosystems ACE™ HDL-C reagent is substantially equivalent to the Centers for Disease Control Reference Method and the predicate device, the Genzyme N-geneous HDL 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.



MAY 21 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Steve Dalessio
Manager, Quality Assurance & Regulatory Affairs
Schiapparelli Biosystems, Inc.
368 Passaic Avenue
Fairfield, New Jersey 07004

Re: K971526
ACE HDL-C Reagent
Regulatory Class: I & II
Product Code: LBS, JIX, JJY
Dated: April 23, 1997
Received: April 28, 1997

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

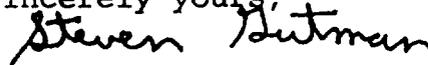
Page 2

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

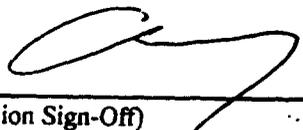
510(k) Number (if known): _____

Device Name: ACE HDL-C REAGENT

Indications For Use:

This in vitro diagnostic product is intended for the quantitative determination of HDL cholesterol in human serum.

Numerous studies have shown an inverse relationship between serum HDL cholesterol and the risk of coronary heart disease. HDL cholesterol also has an important role in the pathogenesis of atherosclerosis.



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971526

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)