NOV 30 1999

K993310

510(k) Summary
For Apolipoprotein Control Serum CHD

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.

Submitter's Name: Donna A. Wolf
Dade Behring Inc.
P. O. Box 6101
Newark, Delaware 19714
Tel: 302-631-0384

Preparation Date: September 30, 1999

Device Name / Classification: Apolipoprotein Control Serum CHD
Quality Control Material (assayed)

Predicate Device: Apolipoprotein Control Serum (K903687)

Device Description: Apolipoprotein Control Serum CHD is a lyophilized reagent prepared from human serum with stabilizers and preservative. The product is calibrated against different protein standard preparations including in-house and commercially available reference preparations.

Device Intended Use: Apolipoprotein Control Serum CHD is used as an assayed control for accuracy and precision in the quantitative immunochemical determination of apolipoprotein A-I and B by radial immunodiffusion, apolipoprotein A-I, AII*, B, E* and CRP with the Behring Nephelometer Systems, or apolipoprotein A-I, B and Myoglobin with the TurbiTime System™.
*Reagents for these determinations are not available in the USA.

Comparison to Predicate Device:

	Apolipoprotein Control Serum CHD (modified)	Apolipoprotein Control Serum (K903687)
Intended Use	Assayed control	Assayed control
Analytes	Apolipoprotein A-1, AII, B, E, myoglobin and CRP	Apolipoprotein A-1, AII, B, E, and myoglobin
Matrix	Stabilized reagent from human serum	Stabilized reagent from human serum
Form	Lyophilized	Lyophilized
Volume	0.5 ml per vial	0.5 ml per vial

Comments on Substantial Equivalence: Both the Apolipoprotein Control Serum CHD and the Apolipoprotein Control are similar products. Both products are intended for use as a quality control material to monitor accuracy and precision of human serum protein assays using radial immunodiffusion, the Behring Nephelometer Systems, and the TurbiTime System™.

Conclusion: The Apolipoprotein Control Serum CHD is substantially equivalent to the Apolipoprotein Control Serum based on the comparison summarized above.

Donna A. Wolf
Regulatory Affairs and
Compliance Specialist
Date: September 30, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 30 1999

Ms. Donna A. Wolf
Regulatory Affairs Specialist, Biology
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K993310
Trade Name: Apolipoprotein Control Serum CHD
Regulatory Class: I
Product Code: JJY
Dated: September 30, 1999
Received: October 4, 1999

Dear Ms. Wolf:

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 at (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

Dade Behring Inc.
Apolipoprotein Control
510(k) Notification

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Indications for Use Statement

Device Name: Apolipoprotein Control Serum CHD

Indications for Use:

Apolipoprotein Control Serum CHD is used as an assayed control for accuracy and precision in the quantitative immunochemical determination of

Apolipoprotein A-I and B by radial immunodiffusion;

Apolipoprotein A-I, AII*, B, E* and CRP with the Behring Nephelometer Systems;

and Apolipoprotein A-I, B and Myoglobin with the TurbiTime System™.

* Reagents for these determinations are not available in USA

Peter E Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993310

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21CFR801.109)

Over-The-Counter-Use ____
(Optional Format 1-2-96)

CONFIDENTIAL