AUG 1 - 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Lipoprotein Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051619

1. Submitter's name, address and telephone number:

Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
A subsidiary of Bayer Corporation
511 Benedict Avenue
Tarrytown, NY 10591
TEL: 914-524-3494
FAX: 914-524-2500
Email: andres.holle.b@bayer.com

2. Name of the device:

a) Classification Names: Calibrator, §862.1150
Classification: Class II
Product Code: 75 JIX

b) Common name: Calibrator for multiple assays

c) Proprietary name: Lipoprotein Calibrator

d) The device:

Product Name	Calibrator Part # / BAN Number
Lipoprotein Calibrator	00848903

e) Contract Manufacturing Site:
Medical Analysis Systems, Inc. (MAS)
5300 Adolfo Road
Camarillo, CA 93012

3. Predicate Device:

Product Name	Calibrator Part #
Lipoprotein Calibrator	00848903

Contract Manufacturing Site:
Medical Analysis Systems, Inc. (MAS)
5300 Adolfo Road
Camarillo, CA 93012

510(k) Number: K031682

4. Description of the device:

The Lipoprotein Calibrator is a human serum based solution containing various non human and human constituents.

5. Statement of Intended Use

Bayer Lipoprotein Calibrator is intended for in vitro diagnostic use to calibrate Apolipoprotein A1, Apolipoprotein B assays and Direct HDL on the ADVIA IMS Chemistry systems.

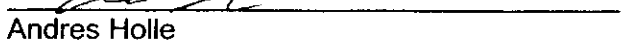
6. Product Performance

The stability of the Lipoprotein calibrator values has been validated according to Bayer procedures and is based on the results of three separate lots of calibrator material. The performance of the calibrator is similar to other products in commercial distribution intended for similar use.

7. Substantial Equivalence:

Feature	Predicate Lipoprotein Calibrator (K031682)	Proposed Lipoprotein Calibrator (addition of assigned value for Direct HDL Cholesterol Method)
Intended Use	Bayer Lipoprotein Calibrator is intended for in vitro diagnostic use to calibrate apolipoprotein A1 and apolipoprotein B assays on the ADVIA IMS chemistry systems	Bayer Lipoprotein Calibrator is intended for in vitro diagnostic use to calibrate apolipoprotein A1 , apolipoprotein B and Direct HDL cholesterol assays on the ADVIA IMS chemistry systems
Format	Lyophilized mixture of human and bovine serum base to which appropriate human and bovine constituents have been added to achieve specific concentrations.	Same
Constituent Analytes	• Apolipoprotein A1 • Apolipoprotein B • HDL Cholesterol*	• Apolipoprotein A1 • Apolipoprotein B • HDL Cholesterol
Stability	• Stable at 2-8°C until the expiration date printed on the label. • Stable 3 days when reconstituted according to directions when refrigerated at 2-8°C	Same
Levels	Six levels for Apolipoprotein A1 and Apolipoprotein B	Six levels for Apolipoprotein A1 and Apolipoprotein B and a single level for the Direct HDL Cholesterol method

* Please note: The predicate device already contained HDL Cholesterol as an analyte so the manufacturing process did not change, however Bayer did not assign any values for Direct HDL Cholesterol method at the time of the predicate device submission.



Date 6/14/2005

Andres Holle
Manager Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 - 2005

Mr. Andres Holle
Manager, Regulatory Affairs
Bayer HealthCare LLC
511 Benedict Avenue
Tarrytown, NY 10591

Re: k051619
Trade/Device Name: Lipoprotein for Multiple Analytes
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: June 9, 2005
Received: June 17, 2005

Dear Mr. Holle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ- Division
D.O.

Indications for Use

510(k) Number (if known): K051619

Device Name: Lipoprotein Calibrator

Indications For Use:

The *Bayer Lipoprotein Calibrator* is intended for *in vitro* diagnostic use to calibrate Apolipoprotein A1, Apolipoprotein B and the Direct HDL assays on the ADVIA® IMS Chemistry systems.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051619