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K983849

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

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: Rebecca S. Ayash
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Building 500, Mailbox 514
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: 10/29/98

Device Name: Dimension® Automated High Density Lipoprotein Cholesterol (AHDL) Flex™ reagent cartridge

Classification Name: Colorimetric Method, Lipoprotein

Predicate Device: Dimension® High Density Lipoprotein Cholesterol (HDL) Assay

Device Description: The AHDL method for the Dimension® clinical chemistry system is a homogeneous method for direct measurement of high density lipoprotein (HDL) cholesterol levels without the need for off-line pretreatment or centrifugation steps.

The method is in a two-reagent format and depends on the properties of a unique detergent, which solubilizes only the HDL particles, thus releasing HDL cholesterol to react with cholesterol esterase to produce color. In addition to selectively disrupting the HDL particles, this detergent also inhibits the reaction of the cholesterol enzymes with LDL, VLDL and chylomicrons by adsorbing to their surfaces. A polyanion is contained in the first reagent to assist with complexing LDL, VLDL and chylomicrons, further enhancing the selectivity of the detergent and enzymes for HDL cholesterol.

$$\text{LDL, VLDL, Chylomicrons} \xrightarrow[\text{Polyanion}]{\text{Detergent}} \text{Stable Complexes}$$

$$\text{HDL} \xrightarrow{\text{Detergent}} \text{HDL Disrupted}$$

$$\text{HDL Cholesterol} \xrightarrow[\text{Cholesterol oxidase}]{\text{Cholesterol esterase}} \Delta' \text{ Cholestenone} + H_2O_2$$

$$H_2O_2 + \text{DSBmT} + 4\text{AA} \xrightarrow[\text{Peroxidase}]{} \text{Color development}$$

DSBmT = N,N-bis(4-sulphobutyl) m-toluidine-disodium

Intended Use: The AHDL method for the Dimension® clinical chemistry system is a device used to quantitatively measure High Density Lipoprotein Cholesterol in human serum or plasma. AHDL measurements may be used in the diagnosis and treatment of lipid disorders.

Comparison to Predicate Device:

Item	Dimension® AHDL Method	Dimension® HDL Method
Technology	Direct homogeneous	Manual phosphotungsate precipitation
Detection	Enzymatic colorimetric bichromatic endpoint	Enzymatic colorimetric polychromatic endpoint
Separation	Polyanions, detergent	Centrifugation
Sample Size	3 µL	250 µL
Sample Type	serum or plasma	serum or plasma
Intended Use	For the measurement of high density lipoprotein cholesterol	For the measurement of high density lipoprotein cholesterol

Comments on Substantial Equivalence: Split sample comparison between the Dimension® AHDL method and the Dimension® HDL assay gave a correlation coefficient of 0.991, slope of 0.931, and an intercept of 0.811 mg /dL when tested with 272 clinical patient samples ranging from 9 - 105 mg/dL.

Conclusion: The AHDL Method for the Dimension® clinical chemistry system is substantially equivalent in principle and performance to the Dimension® HDL method based on the split sample comparison summarized above.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 10/29/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 11 1999

Rebecca S. Ayash
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Glasgow Building 500 Mail Box 514
P.O. box 6101
Newark, DE 19714

Re: K983849
Trade Name: Dimension Automated High Density Lipoprotein Cholesterol Flex™ reagent cartridge
Regulatory Class: I
Product Code: JHM
Dated: October 29, 1998
Received: October 30, 1998

Dear Ms. Ayash:

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

Indications Statement

Device Name: Dimension® Automated High Density Lipoprotein Cholesterol (AHDL) Flex™ reagent cartridge

Indications for Use: The AHDL method for the Dimension® clinical chemistry system is a device used to quantitatively measure High Density Lipoprotein Cholesterol in human serum or plasma. AHDL measurements are used as an aid in the diagnosis and treatment of lipid disorders.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 10/29/98

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K983849
510(k) Number

Patricia Brinkley for Dr. Carol Montgomery
Division Sign-Off
Office of Device Evaluation

✓ prescription use