FEB 21

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k073072

### 1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

| | |
|---|---|
| Manufacturer: | Dade Behring Inc.<br>P.O. Box 6101<br>Newark, DE 19714 |
| Contact Information: | Dade Behring Inc.<br>P.O. Box 6101<br>Newark, DE 19714<br>Attn: Pamela A. Jurga<br>Tel: 302-631-8891 |
| Date of Preparation: | October 30, 2007 |

### 2. Device Name / Classification

- Dimension® AHDL Flex® reagent cartridge/ Class I

### 3. Identification of the Predicate Device

- Dimension® AHDL Flex® reagent cartridge (K032798)

**FDA Guidance Document(s):**

- "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff "- 4/25/2006

### 4. Device Description(s):

The AHDL assay measures HDL cholesterol levels directly without the need for sample pretreatment or specialized centrifugation steps, using a two reagent format. In the first reaction, chylomicrons, VLDL and LDL form water soluble complexes with dextran sulfate in the presence of magnesium sulfate. These complexes are resistant to the polyethylene glycol (PEG)-modified cholesterol esterase

and cholesterol oxidase that react with HDL cholesterol. In the presence of oxygen, the HDL cholesterol is oxidized to Δ4-cholestenone and hydrogen peroxide. The generated hydrogen peroxide then reacts with 4-aminoantipyrine and sodium N-(2-hydroxy-3-sulfopropyl)-3,5-dimethoxyaniline (HSDA) in the presence of peroxidase to form a colored dye that is measured using a bichromatic (600/700 nm) endpoint technique. The color intensity of the dye is directly proportional to the serum HDL-C concentration.

## 5. Device Intended Use:

The AHDL method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension® clinical chemistry system. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease.

## 6. Medical device to which equivalence is claimed:

**Substantial Equivalence:**

This product is substantially equivalent to other HDL test systems, such as the Dimension® AHDL Flex® reagent cartridge (K032798).

**Comparison to Predicate Device:**

The proposed Dade Behring Dimension AHDL method and the predicate Dimension® AHDL method are both *in vitro* diagnostic assays intended for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension® clinical chemistry system.

A comparison summary of the features of the products is included in the following table.

**Method:**

| Item | Device | Predicate |
|---|---|---|
| Intended Use | The AHDL method is an *in vitro* diagnostic test for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension® clinical chemistry system. Measurements of HDL-C are used as an aid in the diagnosis of lipid disorders (such as diabetes mellitus), various liver and renal diseases and in the assessment of risk for atherosclerosis and cardiovascular disease. | The AHDL method for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure high-density lipoprotein cholesterol (HDL-C) in human serum and plasma. HDL-C measurements are used as an aid in the diagnosis of lipid disorders |

| Sample Type | Human Serum or Plasma | Human Serum or Plasma |
|---|---|---|
| Sample Size | 3 uL | 3 uL |
| Measurement method | PEG HDL-C (polyethylene modified) | Accelerator Selective Detergent Methodology |
| Measuring Range | 3-150 mg/dL | 3-150 mg/dL |

**Comments on Substantial Equivalence:**

The proposed Dade Behring Dimension AHDL method (DF48B) and the predicate Dimension® AHDL method (DF48A) are both *in vitro* diagnostic assays intended for the quantitative measurement of high-density lipoprotein cholesterol (HDL-C) in human serum and plasma on the Dimension® clinical chemistry system.

Method comparison testing with human serum samples following CLSI Approved Guideline for Method Comparison and Bias Estimation Using Patient Samples; EP9-A2 demonstrates good analytical and clinical agreement between the methods giving the following linear regression statistics:

| **Comparative Method** | **Slope** | **Intercept mg/dL** | **Correlation Coefficient** | **n** |
|---|---|---|---|---|
| Dimension AHDL (DF48A) | 1.04 | -3.9 | 1.00 | 130 |

**Conclusion:**
The proposed Dade Behring Dimension AHDL method (DF48B)and the predicate Dimension® AHDL method (DF48A) (K032798) are substantially equivalent based on their intended use and performance characteristics as described above.

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
October 30, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 21 2008

Dade Behring, Inc.
Glasgow Business Community
c/o Ms. Pamela A. Jurga
Regulatory Affairs and Compliance Manager
P.O. Box 6101, Bldg. 500, M/S 514
Newark, DE 19714-6101

Re: k073072
Trade/Device Name: Dimension® AHDL Flex® Reagent Cartridge
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system.
Regulatory Class: Class I, meets the limitation to exemption in 862.9(c)(4)
Product Code: JHM
Dated: January 25, 2008
Received: January 28, 2008

Dear Ms. Jurga:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** k073072

**Indications For Use:**

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**Prescription Use** __√_____ **AND/OR** **Over-the-counter Use** _____
**(Per 21 CFR 801 Subpart D)** **(21 CFR 801 Subpart C)**

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

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



Division Sign-Off
Jean Cooper, D.V.M.
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) k073072