OCT 3 0 2003

**"revised" Dimension® Automated HDLCholesterol (AHDL)**
**Flex® reagent cartridge (DF48A)**

**510(k) Summary**

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.

The assigned 510(k) number is : K032798

**Submitter's Name**
Andrea M. Tasker
Dade Behring Inc.
Building 500, Mailbox 514
P.O.Box 6101
Newark, DE 19714-6101

**Submission Preparation Date**:
September 8, 2003

**Device Name and Classification**

| | |
|---|---|
| Trade Name: | Dimension® Automated HDL Cholesterol(AHDL) Flex® reagent cartridge |
| Common/Usual Name: | Colorimetric Method, Lipoprotein |
| Classification: | Class I |
| Product Code: | JHM |

**Predicate Device**
Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48) FDA Document Control No. K983849

**Device Description**
The Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48A) is an *in vitro* diagnostic device that consists of prepackaged reagents in a plastic cartridge (Flex®) for use on the Dade Behring Dimension® clinical chemistry system.

**Intended Use**
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.

**Comparison to Predicate Device**

| | "Current" Dimension® Automated HDL Cholesterol Flex® reagent cartridge (DF48) | "Revised" Dimension® Automated HDL Cholesterol Flex® reagent cartridge (DF48A) |
|---|---|---|
| **Intended Use** | For the measurement of high density lipoprotein cholesterol | For the measurement of high density lipoprotein cholesterol |
| **Sample Type** | Human Serum or Plasma | Human Serum or Plasma |
| **Sample Volume** | 3uL | 3uL |
| **Detection** | Enzymatic Colormetric Bichromatic Endpoint | Enzymatic Colormetric Bichromatic Endpoint |
| **Wavelengths** | 600 and 700 nm | 600 and 700nm |
| **Reagent 1 Vol.** | 300uL | 300uL |
| **Reagent 2 Vol.** | 100uL | 100uL |
| **Methodology** | Polyanion Selective Detergent Methodology | Accelerator Selective Detergent Methodology |

**Comments on Substantial Equivalence**

Split sample comparison between the "current" Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48) and the "revised" Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48A) gave the following correlation statistics, when tested with clinical patient samples.

| Revised AHDL (DF48A) vs. | **Slope** | **Intercept mg/dL [mmol/L]** | **Correlation Coefficient** | **n** |
|---|---|---|---|---|
| Current AHDL (DF48) | 1.04 | -3.38 [-0.09] | 0.995 | 101 |

**Conclusion**

The results of performance studies demonstrate that the "revised" Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48A) is substantially equivalent to the Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48) FDA Document Control No. K983849 .

Andrea M. Tasker
Senior Regulatory Affairs and Compliance Specialist
Date: September 8, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Andrea M. Tasker
Senior Regulatory Affairs and Compliance Specialist
Dade Behring, Inc.
Chemistry/Immunochemistry
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Newark, DE 19714

OCT 3 0 2003

Re: k032798
Trade/Device Name: Dimension® Automated HDL Cholesterol (AHDL) Flex® reagent cartridge (DF48A)
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I
Product Code: JHM
Dated: September 8, 2003
Received: September 9, 2003

Dear Ms. Tasker:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

**Indications For Use Statement**

K032798

**Device Name:**

Dimension® Automated HDL Cholesterol (AHDL)

Flex® reagent cartridge (DF48A)

**Indications for Use:**

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.

Andrea M. Tasker

Senior Regulatory Affairs and Compliance Specialist

September 8, 2003

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** X **OR** **Over-the-counter Use**_____

**(Per 21 CFR 801.109)** **(Optional format 1-2-96)**

Carol C Benson for Jean Cooper, DVM

**Division Sign-Off**

**Office of In Vitro Diagnostic Device Evaluation and Safety**



**510(k)** K032798