FEB 2 3 2007

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: K063154

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

Manufacturer:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Pamela A. Jurga Tel: 302-631-8891
Date of Preparation:	December 15, 2006

2. Device Name / Classification

- Dimension Vista™ BHCG reagent cartridge/ Class II
- Dimension Vista™ BHCG calibrator/ Class II

3. Identification of the Predicate Device

- Dimension® Human Chorionic Gonadotropin (HCG) method and calibrator. (K970387/K970396).

FDA Guidance Document(s):

- "Bundling Multiple Devices or Multiple Indications in a Single Submission"- 11/26/2003
- "Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) in Vitro Diagnostic Devices (IVDs)" 11/06/96

4. Device Description(s):

Method

The BHCG method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI™ technology. The LOCI™ reagents include two synthetic bead reagents and a biotinylated anti-βhCG monoclonal antibody fragment. The first bead reagent (Sensibeads) is coated with streptavidin and

contains photosensitizer dye. The second bead reagent (Chemibeads) is coated with a second anti-βhCG monoclonal antibody and contains chemiluminescent dye. Sample is incubated with Chemibeads and biotinylated antibody to form a bead-βhCG-biotinylated antibody sandwich. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses to the Chemibeads and triggers a chemiluminescent reaction. The resulting chemiluminescent signal is measured at 612 nm and is directly proportional to the nicked and non-nicked free, and nicked and non-nicked intact β human chorionic gonadotropin concentration in the sample.

Calibrator
The BHCG Calibrator is a liquid product containing human chorionic gonadotropin in a bovine calf serum matrix with stabilizers and preservative. The kit consists of twelve vials, two each of six levels containing 2.0 mL per vial for level A, 1.0 mL per vial for levels B, C, D, and E, 1.5 mL per vial for level F. Description of the manufacturing, value assignment and stability testing processes are provided.

5. Device Intended Use:

Method
The BHCG method is an *in vitro* diagnostic assay for the quantitative measurement of total Beta (β) human chorionic gonadotropin: both the intact hCG dimer and the free β subunit of human chorionic gonadotropin hormone in human serum and plasma on the Dimension Vista™ system. Measurements of β human chorionic gonadotropin are used for the early detection of pregnancy.

Calibrator
The BHCG calibrator is an *in vitro* diagnostic product for the calibration of the Total Beta (β) Human Chorionic Gonadotropin (BHCG) method for the Dimension Vista™ System.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:
These products are substantially equivalent to other HCG test systems, such as the Dimension® Human Chorionic Gonadotropin (HCG) method and calibrator.
(K970387/K970396).

Comparison to Predicate Device:

The proposed Dade Behring Dimension Vista™ BHCG method and the predicate Dade Behring Dimension® Human Chorionic Gonadotropin (HCG) method are both *in vitro* diagnostic immunoassays intended for the measurement of human chorionic gonadotropin hormone in human serum and plasma.

The Dade Behring Dimension Vista™ BHCG calibrator and the predicate Dade Behring Dimension® Human Chorionic Gonadotropin (HCG) calibrator are both calibrators intended to calibrate their associated HCG methods.

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

Feature	Dimension Vista™ BHCG	Dimension® HCG (K970387)
Intended Use	The BHCG method is an *in vitro* diagnostic assay for the quantitative measurement of total Beta (β) human chorionic gonadotropin: both the intact hCG dimer and the free β subunit of human chorionic gonadotropin hormone in human serum and plasma on the Dimension Vista™ system. Measurements of β human chorionic gonadotropin are used for the early detection of pregnancy.	The HCG method for the Dimension® clinical chemistry system with the heterogeneous immunoassay module is intended to quantitatively measure intact human chorionic gonadotropin in serum and plasma for the early detection of pregnancy.
Assay Type	immunoassay (chemiluminescent)	immunoassay (photometric)
Sample type	Serum and plasma	Serum and plasma
Reportable Range	1-1000 mIU/mL	1-1000 mIU/mL
Analytical Sensitivity	≤ 1 mIU/mL	≤ 1 mIU/mL
Sample Volume	2 µL	40 µL

Calibrator:

Feature	Dimension Vista™ βhCG Calibrator	Dimension® HCG Calibrator (K970396)
Intended Use	The BHCG calibrator is an *in vitro* diagnostic product for the calibration of the Total Beta (β) Human Chorionic Gonadotropin method for the Dimension Vista™ System.	The Human Chorionic Gonadotropin Calibrator is an *in vitro* diagnostic product intended to be used to calibrate the Human chorionic gonadotropin (HCG Cat. No. RF430 and LHCG Cat, No. RF530) methods for the Dimension® clinical chemistry system with the heterogeneous immunoassay module. This product was designed to meet the needs of users to assure accurate results over the assay range of this

		method.
Analyte	Human urine chorionic gonadotropin	Human urine chorionic gonadotropin
Matrix	Bovine calf serum	Equine serum
Form	Liquid	Lyophilized
Volume	12 vials, 2 at each level, 2.0 mL per vial for level A, 1.0 mL per vial for level B, C, D, E, 1.5 mL per vial for level F	10 vials, 2 at each level, reconstituted volume 2 mL for each level
Levels	6 levels (0, 14, 28, 160, 550, 1100 mIU/mL)	5 levels (0, 25, 155, 522, 1120 mIU/mL)

Comments on Substantial Equivalence:

Method
The Dade Behring Dimension Vista™ BHCG method and the Dade Behring Dimension® Human Chorionic Gonadotropin (HCG) method are both *in vitro* diagnostic immunoassays intended for the measurement of human chorionic gonadotropin hormone in human serum and plasma. Comparative data for human serum and plasma samples demonstrate good analytical and clinical agreement between the methods.

Calibrator
The Dade Behring Dimension Vista™ BHCG calibrator is similar to other calibrator products associated with their assays, such as the Dade Behring Dimension® Human Chorionic Gonadotropin (HCG) calibrator.

Conclusion:
The Dade Behring Dimension Vista™ BHCG method and the predicate Dade Behring Dimension® Human Chorionic Gonadotropin (HCG) method (K970387) are substantially equivalent based on their intended use and performance characteristics as described above. The calibrator products are also substantially equivalent in its design and intended use with their respective assay systems (K970396).

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
December 15, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 23 2007

Pamela A Jurga
Dade Behring, Inc.
P.O. Box 6101 Bldg. 500; M.S.514
Newark, DE 19714-6101

Re: k063754
Trade/Device Name: Dimension® Vista™ BHCG Flex® reagent cartridge and Dimension® Vista™ BHCG calibrator
Regulation Number: 21 CFR § 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA, JIT
Dated: December 15, 2006
Received: December 19, 2006

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): K063754

Device Name:

- Dimension® Vista™ BHCG Flex® reagent cartridge method
- Dimension® Vista™ BHCG calibrator

Indications For Use:

Method

The BHCG method is an *in vitro* diagnostic assay for the quantitative measurement of total Beta (β) human chorionic gonadotropin: both the intact hCG dimer and the free β subunit of human chorionic gonadotropin hormone in human serum and plasma on the Dimension Vista™ system. Measurements of β human chorionic gonadotropin are used for the early detection of pregnancy.

Calibrator

The BHCG calibrator is an *in vitro* diagnostic product for the calibration of the Beta Human Chorionic Gonadotropin method for the Dimension Vista™ System.

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

(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

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K063754