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: K071767

AUG 2 4 2007

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:	June 28, 2007

2. Device Name / Classification

- Dimension® PBNP reagent cartridge/ Class II

3. Identification of the Predicate Device

- Dimension® PBNP reagent cartridge/ Class II (K041417/K042347).

FDA Guidance Document(s):

- "Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers" - 11/30/2000
- "Deciding When to Submit a 510(k) for a Change to an Existing Device"- 1/10/1997

4. Device Description(s):

The PBNP method is a one-step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles coated with monoclonal antibodies, which recognize an epitope located in the N-terminal part of proBNP, and a conjugate reagent [alkaline phosphatase (ALP)] labeled monoclonal antibody specific for a second independent epitope on NT-proBNP, to form a particle/NT-proBNP/conjugate sandwich. Unbound conjugate is removed by magnetic separation and washing. After separation and washing, the particle/NT-proBNP/conjugate sandwich is transferred to the cuvette where the sandwich-bound ALP triggers an amplification cascade.* ALP dephosphorylates synthetic flavin adenine dinucleotide phosphate (FADP) to produce FAD. FAD

binds to apo D-amino acid oxidase and converts it to active holo D-amino acid oxidase. Each molecule of holo D-amino acid oxidase produces multiple molecules of hydrogen peroxide (H_2O_2). H_2O_2 in the presence of horseradish peroxidase (HRP), converts 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4-AAP) to a colored product that absorbs at 510 nm. The color change measured is directly proportional to the concentration of NT-proBNP present in the patient sample.

*Technology licensed from London Biotechnology, Ltd., London, U.K.

5. Device Intended Use:

The PBNP assay used on the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic assay for the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum or plasma. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:
This product is substantially equivalent to other B-type natriuretic peptide test systems, such as the Dimension® PBNP Flex® reagent cartridge immunoassay (K041417/K042347).

Comparison to Predicate Device:

The modified Dade Behring Dimension® PBNP method and the current Dade Behring Dimension® PBNP method are both *in vitro* diagnostic immunoassays intended for the quantitative measurement of N-terminal pro-brain natriuretic peptide. A summary of the features of the two methods is included in the following table.

Feature	Dimension® PBNP-mono	Dimension® PBNP (K041417/K042347)
Intended Use	The PBNP assay used on the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic assay for the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum or plasma. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification	The PBNP assay used on the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic assay for the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human plasma. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart

	of patients with acute coronary syndrome and heart failure.	failure.
Assay Type (detection)	immunoassay (chemiluminescent)	immunoassay (chemiluminescent)
Reportable Range	10 - 30,000 pg/mL	10 - 30,000 pg/mL
Antibody	monoclonal (sheep) antibody	polyclonal (sheep) antibody
Cut-off	125 pg/mL for patients less than 75 years and 450 pg/mL for patients 75 years and older	125 pg/mL for patients less than 75 years and 450 pg/mL for patients 75 years and older
Analytical Sensitivity	≤ 10 pg/mL	≤ 10 pg/mL
Functional Sensitivity	≤ 30 pg/mL	≤ 30 pg/mL
Analytical Specificity	Natrecor® shows no significant cross reactivity, 0 or 125 pg/mL NT-proBNP; sixteen other substances show no significant cross reactivity	Natrecor® shows no significant cross reactivity, 0 or 125 pg/mL NT-proBNP; sixteen other substances show no significant cross reactivity
Interferences	No significant interference from: Bilirubin, conj. up to 60 mg/dL bilirubin, unconj. up to 60 mg/dL hemoglobin up to 1000 mg/dL triglycerides up to 3000 mg/dL rheumatoid factors up to 500 IU/mL	No significant interference from: Bilirubin, conj. up to 60 mg/dL bilirubin, unconj. up to 20 mg/dL hemoglobin up to 1000 mg/dL triglycerides up to 3000 mg/dL rheumatoid factors up to 500 IU/mL
Hook Effect	No effect up to 300,000 pg/mL	No effect up to 300,000 pg/mL
Calibration Interval	30 days - same reagent lot	30 days - same reagent lot
Sample Volume	50 uL	50 uL

Comments on Substantial Equivalence:

Both the modified Dade Behring Dimension® PBNP and the current Dade Behring Dimension® PBNP immunoassays are intended for the quantitative determination of NT-proBNP. Comparative data for human samples demonstrate good analytical and clinical agreement between the methods.

Conclusion:

The modified Dade Behring Dimension® PBNP method and the predicate Dade Behring Dimension® PBNP method (K041417/K042347) are substantially equivalent based on their intended use and performance characteristics as described above.

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
June 28, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

AUG 24 2007

Re: k071767
Trade/Device Name: Dimension® NT-proBNP (PBNP) Flex® reagent cartridge method
Regulation Number: 21 CFR§ 862.1117
Regulation Name: B-Type Natriuretic Peptide Test System.
Regulatory Class: Class II
Product Code: NBC
Dated: June 28, 2007
Received: June 29, 2007

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):

Device Name:

Dimension® NT-proBNP (PBNP) Flex® reagent cartridge method

Indications For Use:

The PBNP assay used on the Dimension® clinical chemistry system with the heterogeneous immunoassay module is an *in vitro* diagnostic assay for the quantitative determination of N-terminal pro-brain natriuretic peptide (NT-proBNP) in human serum or plasma. In individuals suspected of having congestive heart failure (CHF), measurements of NT-proBNP are used as an aid in the diagnosis and assessment of severity. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

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)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K071767