K071834

AUG 17 2007

## 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.

**Submitter's Name:** George M. Plummer
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

**Date of Preparation:** June 30, 2007

**Name of Product(s):** Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak

**FDA Classification Name(s):** B-type natriuretic peptide test system

**FDA Guidance Documents:** "Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers" - 11/30/2000

**Predicate Device(s):** Dade Behring Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak (k043476/k060548)

**Device Description(s):**

Method

The Stratus® CS Acute Care™ NT-proBNP method is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal antibody is added to the center portion of a square piece of glass fiber paper in the pBNP TestPak. This antibody recognizes a distinct antigenic site on the NT-proBNP molecule. Sample is then added onto the paper where it reacts with the immobilized antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against a second distinct antigenic site on the NT-proBNP molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound NT-proBNP, forming an antibody-antigen-labeled antibody sandwich. The unbound labeled antibody is later eluted from the field of view of the Stratus® CS analyzer by applying a substrate wash solution to the center of the reaction zone. By including substrate for the enzyme within the wash solution, initiation of enzyme activity occurs simultaneously with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of NT-proBNP in the sample. The reaction rate can then be measured by an optical system that monitors the reaction rate via front surface fluorescence. All data analysis functions are performed by the microprocessor within the analyzer.

**Intended Use:**

Method

The Stratus® CS Acute Care™ NT-proBNP method (pBNP) is an *in vitro* diagnostic test for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in heparanized 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.

**Comparison to Predicate Device:**

A summary of the features of the revised Dade Behring Stratus® CS Acute Care™ pBNP TestPak and the current (predicate) Dade Behring Stratus® CS Acute Care™ pBNP immunoassay (k043476/k060548) is provided in the following charts.

| Feature | Revised Stratus® CS Acute Care™ pBNP | Current Stratus® CS pBNP |
|---|---|---|
| Intended Use | For the *in vitro* quantitative determination of N-terminal pro-brain natriuretic peptide in human plasma as an aid in the diagnosis and assessment of severity of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure. | For the *in vitro* quantitative determination of N-terminal pro-brain natriuretic peptide in human plasma as an aid in the diagnosis and assessment of severity of individuals suspected of having congestive heart failure. The test is further indicated for the risk stratification of patients with acute coronary syndrome and heart failure. |
| Assay Type (detection) | fluorometric immunoassay | fluorometric immunoassay |
| Reportable Range | 15- 20,000 pg/mL | 15- 20,000 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 | ≤15 pg/mL | ≤15 pg/mL |
| Functional Sensitivity | ≤ 50 pg/mL | ≤ 50 pg/mL |

| | | |
|---|---|---|
| Analytical Specificity | The pharmaceutical Natrecor® shows no significant cross reactivity at 0 and 125 pg/mL NT-proBNP; sixteen other substances also show no significant cross reactivity | The pharmaceutical Natrecor® shows no significant cross reactivity at 0 and 125 pg/mL NT-proBNP; sixteen other substances also show no significant cross reactivity |
| Interferences | No significant interference from: bilirubin, conj. up to 60 mg/dL bilirubin, unconjugated up to 60 mg/dL, hemoglobin up to 1000 mg/dL, lipemia up to 3000 mg/dL, rheumatoid factors up to 500 IU/mL | No significant interference from: bilirubin, conj. up to 60 mg/dL bilirubin, unconjugated up to 60 mg/dL, hemoglobin up to 1000 mg/dL, triglycerides up to 3000 mg/dL, rheumatoid factors up to 750 IU/mL |
| Hook Effect | No high dose effect ( up to 833,585 pg/mL) | No high dose effect ( up to 1,400,000 pg/mL) |
| Calibration Interval | Calibration curve updated for each lot, using one level and every 30 days, thereafter with the same reagent lot. After calibration update at completion of each test, recovered values are calculated from stored calibration coefficients. | Calibration curve updated for each lot, using one level and every 30 days, thereafter with the same reagent lot. After calibration update at completion of each test, recovered values are calculated from stored calibration coefficients. |
| Sample Volume | 50 uL | 50 uL |

Method performance Summary:

**Analytical Results**

Method Comparison

A split sample method comparison demonstrated good agreement between the revised Dade Behring Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak method and the current (predicate) Dade Behring pBNP TestPak method with heparinized plasma patient samples.

| Comparative Method | Slope | Intercept (pg/mL) | Correlation Coefficient | n |
|---|---|---|---|---|
| Dade Behring pBNP | 1.02 | 8.2 | 0.99 | 148 |

The model equation for Passing-Bablok linear regression statistics is: [results for revised Stratus® CS pBNP] = slope x [comparative method results] + intercept. The range of NT-proBNP values for the monoclonal method in the correlation study was: 15.8 – 18914.2 pg/mL.

Lithium Heparin versus Sodium Heparin

Comparison of lithium heparin versus sodium heparin samples on the Stratus® CS system showed very good agreement. Fifty-one samples were tested in duplicate. The lithium heparin values ranged from

31.2 to 16, 445 pg/mL and sodium heparin values from 32.2 to 17,769 pg/mL. A linear regression gave a slope of 1.06, an intercept of -75 pg /mL and a correlation coefficient of 0.997.

**Comments on Substantial Equivalence:**
Both the revised Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak and the current Dade Behring pBNP immunoassays are intended for the quantitative determination of NT-proBNP. Comparative data for human plasma samples demonstrate good analytical agreement between the methods.

**Conclusion:**
The revised Dade Behring ® CS Acute Care™ NT-proBNP (pBNP) TestPak and the current (predicate) Dade Behring pBNP immunoassays (k043476/k060548) are substantially equivalent based on their intended use and performance characteristics as described above.

George M. Plummer
Regulatory Affairs and Compliance Manager
June 30, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 17 2007

Dade Behring Inc.
c/o Mr. George M. Plummer
Regulatory Affairs & Compliance Manager
Bldg. 400, M.S. 514
P.O. Box 6101
Newark, DE 19714-6101

Re: k071834
Trade/Device Name: Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak
Regulation Number: 21 CFR §862.1117
Regulation Name: B-type Natriuretic Peptide Test System.
Regulatory Class: Class II
Product Code: NBC
Dated: June 30, 2007
Received: July 03, 2007

Dear Mr. Plummer:

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 STATEMENT**

**510(k) Number (If Known):** k071834

**Device(s) Name(s):**

Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak

**Indications for Use:**

The Stratus® CS Acute Care™ NT-proBNP method (pBNP) 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 failure. This method is for use by trained health care professionals on the Stratus® CS Stat Fluorometric Analyzer in the clinical laboratory and point of care (POC) settings.

**Prescription Use** ___X__ **and/or** **Over-the-counter Use** _____
**(Part 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)**

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K071834