APR 6 2006

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: K060548

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:	February 28, 2006

2. Device Name / Classification

- Stratus® CS Acute Care™ βhCG TestPak / Class II
- Stratus® CS Acute Care™ βhCG CalPak (the assay calibrator) / Class II
- Stratus® CS Acute Care™ βhCG DilPak (the assay diluent) / Class II
- Stratus® CS Acute Care™ NT-proBNP (pBNP) TestPak / Class II
- Stratus® CS Acute Care™ NT-proBNP (pBNP) CalPak (the assay calibrator) / Class II
- Stratus® CS Acute Care™ NT-proBNP (pBNP) DilPak (the assay diluent) / Class II

3. Identification of the Predicate Device

- Dade Behring Stratus® CS βhCG TestPak, CalPak and DilPak K003696
- Dade Behring Stratus® CS pBNP Acute Care™ TestPak, CalPak and DilPak K043476

FDA Guidance Document(s):

- "Bundling Multiple Devices or Multiple Indications in a Single Submission" - 11/26/2003
- "Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers" - 11/30/2000

4. Device Description(s):

βhCG

Method

The Stratus® CS Acute Care™ βhCG method is a solid phase, two-site sandwich fluorometric immunoassay based upon Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal βhCG antibody is added to the center portion of a square piece of glass fiber paper in the βhCG TestPak. The dendrimer binds electrostatically to the glass fibers and immobilizes the capture antibody to the paper. Sample is then added, whereupon βhCG reacts with the immobilized antibody. After a short incubation, a conjugate, consisting of enzyme-labeled (alkaline phosphatase) monoclonal antibody directed against a distinct antigenic site on the βhCG molecule, is pipetted onto the reaction zone of the paper. During this second incubation period, the unbound, labeled antibody is radially eluted with a wash solution. By including substrate (4-methylumbelliferyl phosphate) 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 βhCG in the sample.

Utilization of two monoclonal antibodies which are specific for distinct antigenic sites on the β subunit of hCG allows the assay to measure the *total* βhCG in the sample, *vis*, both the intact hCG dimer and the free β subunit. Concentration is 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.

Calibrator

The Stratus® CS Acute Care βhCG calibrator (βhCG CalPak) contains human hCG in a bovine serum matrix with preservatives. The βhCG CalPak is a single-use liquid product which contains one calibrator level at an approximate concentration of 950 mIU/mL* [IU/L] in each of three wells. The kit consists of five CalPaks at a single calibrator level.

Diluent

The Stratus® CS Acute Care βhCG Diluent (βhCG DilPak) contains a liquid buffered bovine protein protein matrix with stabilizers and 0.09% sodium azide. The kit consists of 5 DilPaks with diluent in one well.

NT-proBNP

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 polyclonal 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 polyclonal 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.

Calibrator
The Stratus® CS Acute Care pBNP Calibrator is a frozen liquid product containing synthetic human NT-proBNP in a bovine albumin matrix with stabilizers and preservative. The kit consists of five CalPaks at a single calibrator level. Each CalPak contains calibrator reagent in three wells.

Diluent
The Stratus® CS Acute Care pBNP Diluent is a refrigerated product containing a buffered bovine protein matrix with stabilizers and preservative. The kit consists of 5 DilPaks with diluent in one well

5. Device Intended Use:

βhCG
Method
The Stratus® CS Acute Care™ βhCG method is an *in vitro* diagnostic test for the quantitative measurement of the total beta subunit, *vis*, both the intact hCG dimer and the free β subunit, of the human chorionic gonadotropin hormone in heparinized plasma. βhCG is used for the early detection of pregnancy. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

Calibrator
The Stratus® CS Acute Care™ βhCG Calibrator (βhCG CalPak), Cat. No. CBHCG-C is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ βhCG method.

Diluent
The Stratus® CS Acute Care™ βhCG Dilution Pak (βhCG DilPak), Cat. No. CBHCG-D is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ βhCG TestPak CAT. NO. CBHCG, for the measurement of samples with elevated levels of βhCG .

NT-proBNP
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 heparinized 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 in the clinical laboratory and point of care (POC) settings.

Calibrator
The Stratus® CS Acute Care™ NT-proBNP Calibrator (pBNP CalPak)), CAT. NO. CPBNP-C is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ NT-proBNP (pBNP) method.

Diluent
The Stratus® CS Acute Care™ NT-proBNP Dilution Pak (pBNP DilPak), CAT. NO. CPBNP-D is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ pBNP TestPak, REF CPBNP, for the measurement of samples with elevated levels of NT-proBNP .

6. Medical device to which equivalence is claimed:

Substantial Equivalence:
The products are substantially equivalent to the commercial Dade Behring Stratus® CS βhCG and NT-proBNP TestPaks, CalPaks and DilPaks.

βhCG TestPak, CalPak and DilPak	K003696
pBNP Acute Care ™ TestPak, CalPak and DilPak	K043476

βHCG
Method
The Stratus® CS Acute Care™ βhCG Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS βhCG TestPak (K003696). Both assays are *in vitro* diagnostic tests for the quantitative measurement of the total beta subunit, *vis*, both the intact hCG dimer and the free β subunit, of the human chorionic gonadotropin hormone in heparinized plasma and are used for the early detection of pregnancy.

There are no formulation or design changes associated with the Stratus® CS βhCG TestPak intended use change. The two products are identical and use the same manufacturing processes. Labeling changes reflect the new intended use, supporting data and new name in addition to minor format changes.

Precision and accuracy data generated by "non-laboratory" personnel is comparable to precision and accuracy data generated by "laboratory" personnel supporting the addition of point of care to the intended use.

Calibrator
The Stratus® CS Acute Care™ βhCG calibrator (βhCG CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS βhCG CalPak (K003696). Both calibrators are intended to be used to calibrate the Stratus® CS Acute Care™ βhCG assay.

There are no formulation or design changes associated with the Stratus® CS βhCG CalPak name change. The two calibrator products are identical and use the same manufacturing processes. Labeling changes reflect the new name in addition to minor format changes.

Diluent
The Stratus® CS Acute Care™ βhCG Dil Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS βhCG DilPak (K003696). Both diluents are intended to be used in conjunction with the Stratus® CS Acute Care™ βhCG TestPaks for the measurement of samples with elevated levels of βhCG.

There are no formulation or design changes associated with the Stratus® CS βhCG DilPak name change. The two diluent products are identical and use the same manufacturing processes. Labeling changes reflect the new name in addition to minor format changes.

pBNP
Method
The Stratus® CS Acute Care™ pBNP Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus CS Acute Care™ pBNP TestPak (K043476). Both assays are *in vitro* diagnostics test for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in heparinized 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 tests are further indicated for the risk stratification of patients with acute coronary syndrome and heart failure.

There are no formulation or design changes associated with the Stratus® CS pBNP TestPak intended use change. The two products are identical and use the same manufacturing processes. Labeling changes reflect the new intended use and supporting data in addition to minor format changes.

Precision and accuracy data generated by "non-laboratory" personnel is comparable to precision and accuracy data generated by "laboratory" personnel supporting the addition of point of care to the intended use.

Calibrator
The Stratus® CS Acute Care™ NT-proBNP Calibrator (pBNP CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus CS® Acute Care™ pBNP CalPak (K043476). Both calibrators are intended to be used to calibrate the NT-proBNP (pBNP) assay on the Stratus® CS analyzer.

There are no formulation or design changes associated with the Stratus® CS Acute Care™ pBNP CalPak name change. The two calibrator products are identical and use the same manufacturing processes. Labeling changes reflect the new name in addition to minor format changes.

Diluent
The Stratus® CS Acute Care™ pBNP Dil Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS pBNP DilPak (K043476). Both diluents are intended to be used in conjunction with the pBNP TestPak on the Stratus® CS analyzer for the measurement of samples with elevated levels of NT-proBNP.

There are no formulation or design changes associated with the Stratus® CS Acute Care™ Troponin I TestPak intended use change. The two diluent products are identical and use the same manufacturing processes. Labeling changes reflect the new intended use, supporting data and new name in addition to minor format changes.

Comparison to Predicate Device:

The modification of these two methods by adding point of care to the intended use is supported by data included in Section 18 (βhCG) and Section 19 (NT-proBNP).

Method comparison and precision analyses were performed at three different locations (clinical laboratory (LAB), Emergency Department (ED) and Cardiac Care Unit (CCU) within either one (βhCG) or two (NT-proBNP) external evaluation sites. This data and a summary of information on the operators and their training, from either the ED or CCU, i.e. "non-lab" operators, is also included in Sections 18 and 19.

This data supports use of these products by trained health care professionals in the clinical laboratory and point of care (POC) settings.

Conclusion:

The products listed in the following table are substantially equivalent based on their indications for use and performance characteristics. Precision and accuracy data generated by "non-laboratory" personnel is comparable to precision and accuracy data generated by "laboratory" personnel supporting the addition of point of care to the intended use.

Predicate Device	New Device
Dade Behring Stratus® CS βHCG TestPak (K003696)	The Stratus® CS Acute Care™ βHCG TestPak
Stratus® CS βHCG CalPak (K003696)	Stratus® CS Acute Care™ βHCG CalPak
Stratus® CS βHCG DilPak (K003696)	Stratus® CS Acute Care™ βHCG DilPak
Dade Behring Stratus® Acute Care™ pBNP TestPak (K043476)	Stratus® CS Acute Care™ pBNP TestPak
Stratus® CS pBNP CalPak (K043476),	Stratus® CS Acute Care™ pBNP CalPak
Stratus® CS pBNP DilPak (K043476)	Stratus® CS Acute Care™ pBNP DilPak

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
February 28, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 6 2006

Ms. Pamela A. Jurga
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
PO Box 6101, Bldg. 500; M.S. 514
Newark, DE 19714-6101

Re: k060548
Trade/Device Name: Stratus® CS Acute Care™ βhCG TestPak
Stratus® CS Acute Care™ βhCG CalPak
Stratus® CS Acute Care™ βhCG DilPak
Stratus® CS Acute Care™ NT- proBNP (pBNP) TestPak assay
Stratus® CS Acute Care™ NT- proBNP (pBNP) CalPak
Stratus® CS Acute Care™ NT- proBNP (pBNP) DilPak
Regulation Number: 21 CFR§862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: DHA, NBC, JIT
Dated: February 28, 2006
Received: March 1, 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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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): K060548

Device Name:

- Stratus® CS Acute Care™ βhCG TestPak
- Stratus® CS Acute Care™ βhCG CalPak
- Stratus® CS Acute Care™ βhCG DilPak

Indications For Use:

The Stratus® CS Acute Care™ βhCG method is an *in vitro* diagnostic test for the quantitative measurement of the total beta subunit, *vis.* both the intact hCG dimer and the free β subunit, of the human chorionic gonadotropin hormone in heparinized plasma. βhCG is used for the early detection of pregnancy. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

The Stratus® CS Acute Care™ βhCG Calibrator (βhCG CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ βhCG method.

The Stratus® CS Acute Care™ βhCG Dilution Pak (βhCG DilPak) is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ βhCG TestPak for the measurement of samples with elevated levels of βhCG .

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060548

Indications for Use

510(k) Number (if known): K060548

Device Name:

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

Indications For Use:

The Stratus® CS Acute Care™ NT-proBNP method is an *in vitro* diagnostic test for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP) in heparinized 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 in the clinical laboratory and point of care (POC) settings.

The Stratus® CS Acute Care™ NT-proBNP Calibrator (pBNP CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ NT-proBNP (pBNP) method.

The Stratus® CS Acute Care™ NT-proBNP Dilution Pak (pBNP DilPak) is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ pBNP TestPak for the measurement of samples with elevated levels of NT-proBNP .

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060548