MAR 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: k063356

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:	March 19, 2007

2. Device Name / Classification

- Stratus® CS Acute Care™ D-dimer (DDMR) TestPak / Class II
- Stratus® CS Acute Care™ D-dimer (DDMR) CalPak (the assay calibrator) / Class II
- Stratus® CS Acute Care™ D-dimer (DDMR) DilPak (the assay diluent)/ Class II

Classification Name:

- Fibrinogen/fibrin degradation products test systems and associated calibrator and diluent

Common/Usual Name:

- D-dimer assay and calibrator and diluent

Proprietary Name:

- Stratus® CS Acute Care™ D-dimer (DDMR) TestPak
- Stratus® CS Acute Care™ D-dimer (DDMR) CalPak
- Stratus® CS Acute Care™ D-dimer (DDMR) DilPak

3. Identification of the Predicate Device

- Dade Behring Stratus® CS DDMR TestPak and DilPak K022976/K051597
- Dade Behring Stratus® CS DDMR CalPak K022977

FDA Guidance Document(s):

- "Bundling Multiple Devices or Multiple Indications in a Single Submission" - 11/26/2003

4. Device Description(s):

Method

The Stratus® CS Acute Care™ DDMR procedure 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 DDMR TestPak. This antibody recognizes a distinct antigenic site on the D-dimer 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 DDMR molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound D-dimer, 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 the enzyme activity occurs simultaneously with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of D-dimer 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™ DDMR calibrator (DDMR CalPak) contains D-dimer in a liquid buffered bovine protein matrix with stabilizers and < 0.1% sodium azide. The DDMR CalPak is a single-use product which contains one calibrator level at an approximate concentration of 3500 ng/mL in each of three wells. The kit consists of five CalPaks at a single calibrator level.

Diluent

The Stratus® CS Acute Care™ DDMR Diluent (DDMR DilPak) contains a liquid buffered bovine protein matrix with stabilizers and < 0.1% sodium azide. The kit consists of 5 DilPaks with diluent in one well.

5. Device Intended Use:

Method

The Stratus® CS Acute Care™ D-dimer (DDMR) method is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma. The Stratus® CS Acute Care™ DDMR method is intended for use as an aid in

the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. 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™ D-dimer Calibrator (DDMR CalPak), Catalog No. CDDMR-C, is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ D-dimer (DDMR) method.

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

6. Medical device to which equivalence is claimed:

Substantial Equivalence:

The products are substantially equivalent to the commercial Dade Behring Stratus® CS DDMR TestPaks, CalPaks and DilPaks.

- Dade Behring Stratus® CS DDMR TestPak and DilPak K022976/K051597
- Dade Behring Stratus® CS DDMR CalPak K022977

Method
The Stratus® CS Acute Care™ DDMR Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS DDMR TestPak (K022976/K051597). Both assays are *in vitro* diagnostic tests for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma. The Stratus® CS DDMR method is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]..

There are no formulation or design changes associated with the DDMR 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™ DDMR calibrator (DDMR CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS DDMR CalPak (K022977). Both calibrators are intended to be used to calibrate the DDMR assay.

There are no formulation or design changes associated with the DDMR 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™ DDMR Dil Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS DDMR DilPak (K022976). Both diluents are intended to be used in conjunction with the DDMR TestPaks for the measurement of samples with elevated levels of D-Dimer.

There are no formulation or design changes associated with DDMR 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.

Comparison to Predicate Device:

Method comparison and precision analyses were performed at three different locations (clinical laboratory (LAB, Emergency Department (ED) and Cardiac Care Unit (CCU) within three external evaluation sites.

Reproducibility
Point of Care Data Subset[1,2]

Point of Care Site 1

Locations / Level	Mean (ng/mL) [µg/L] FEU	WR SD (%CV)	Total SD (%CV)
Lab – Plasma Pool L1	481.6	12.48 (2.6)	16.12 (3.3)
ED – Plasma Pool L1	526.4	22.06 (4.2)	22.85 (4.3)
CCU – Plasma Pool L1	512.9	36.96 (7.2)	36.96 (7.2)
Lab – Plasma Pool L2	2375.8	122.79 (5.2)	228.13 (9.6)
ED – Plasma Pool L2	2539.9	96.45 (3.8)	114.29 (4.5)
CCU – Plasma Pool L2	2541.0	187.67 (7.4)	187.67 (7.4)

Point of Care Site 2

Locations / Level	Mean (ng/mL) [µg/L] FEU	WR SD (%CV)	Total SD (%CV)
Lab – Plasma Pool L1	502.7	15.86 (3.2)	32.11 (6.4)
ED – Plasma Pool L1	468.0	19.29 (4.1)	23.55 (5.0)
CCU – Plasma Pool L1	482.6	8.4 0 (1.7)	10.70 (2.2)
Lab – Plasma Pool L2	2433.5	78.51 (3.2)	120.14 (4.9)
ED – Plasma Pool L2	2350.0	105.89 (4.5)	142.73 (6.1)
CCU – Plasma Pool L2	2356.3	140.46 (6.0)	140.46 (6.0)

Point of Care Site 3

Locations / Level	Mean (ng/mL) [µg/L] FEU	WR SD (%CV)	Total SD (%CV)
Lab – Plasma Pool L1	446.4	10.63 (2.4)	15.94 (3.6)
ED – Plasma Pool L1	484.4	14.80 (3.1)	14.80 (3.1)
CCU – Plasma Pool L1	458.4	16.90 (3.7)	19.72 (4.3)
Lab – Plasma Pool L2	2254.6	86.50 (3.8)	108.48 (4.8)
ED – Plasma Pool L2	2404.4	83.61 (3.5)	94.84 (3.9)
CCU – Plasma Pool L2	2316.7	107.43 (4.6)	107.43 (4.6)

[1] Number of samples tested = 20.
[2] Point of Care precision data collected and analyzed per NCCLS/CLIS EP15-A: 4 reps per day for 5 days.

Correlation
Regression Statistics

POC Site 1	Slope	Intercept ng/mL [µg/L] FEU	Correlation Coefficient	Standard Error of the Regression	n
Lab v ED[3]	1.12 ± 0.01	-8.4 ± 14.3	0.998	78	64
Lab v CCU[3]	1.09 ± 0.02	-32.2 ± 25.6	0.992	139	62
POC Site 2					
Lab v ED[4]	0.93 ± 0.01	-2.01 ± 16.2	0.996	92	67
Lab v CCU[4]	0.91 ± 0.02	-28.9 ± 25.2	0.991	140	65
POC Site 3					
Lab v ED[5]	0.99 ± 0.02	-4.62 ± 28.2	0.989	176	74
Lab v CCU[5]	1.00 ± 0.01	-3.75 ± 22.7	0.994	143	75

[3] range of results = 36– 4220 ng/mL
[4] range of results = 133 – 3974 ng/mL
[5] range of results = 56 – 4778 ng/mL

This data and a summary of information on the operators and their training, from either the ED or CCU, i.e. "non-lab operators supports the 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 DDMR TestPak (K022976/K051597)	The Stratus® CS Acute Care™ DDMR TestPak
Stratus® CS DDMR CalPak (K022977)	Stratus® CS Acute Care™ DDMR CalPak
Stratus® CS DDMR DilPak (K022976)	Stratus® CS Acute Care™ DDMR DilPak

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
March 19, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 3 2007

DADE BEHRING, INC.
C/O Pamela A. Jurga
P.O. Box 6101 Bldg 500; M.S. 514
Newark, Delaware 19714

Re: k063356
Trade/Device Name: Stratus® Acute Care™ DDMR Test Pak
Stratus® Acute Care™ DDMR CalPak
Stratus® Acute Care™ DDMR DilPak
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay
Regulatory Class: Class II
Product Code: DAP
Dated: November 1, 2006
Received: November 7, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. 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 http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC

HFZ-404 510(k) Staff
HFZ- 440 Division
D.O.

Indications for Use

510(k) Number: K063356

Device Name:

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

Indications For Use:

The Stratus® CS Acute Care™ D-dimer (DDMR) method is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma. The Stratus® CS Acute Care™ DDMR method is intended for use as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. 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™ D-dimer Calibrator (DDMR CalPak) Catalog. No. CDDMR-C, is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ D-dimer (DDMR) method.

The Stratus® CS Acute Care™ D-dimer Dilution Pak (DDMR DilPak), Catalog. No. CDDMR-D, is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ DDMR TestPak, Catalog. No. CDDMR for the measurement of samples with elevated levels of D-Dimer.

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) K063356