

MAY 16 2011

**510(k) Summary for  
Stratus CS Acute Care DDMR Assay**

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.

The assigned 510(k) number is: K110303

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

Manufacturer: Siemens Healthcare Diagnostics  
Products GmbH  
Emil-von-Behring Str. 76  
D-35001, Marburg Germany

Contact Information: Siemens Healthcare Diagnostics Inc.  
Glasgow Site  
P.O. Box 6101  
Newark, Delaware 19714  
Attn: Kathleen Dray-Lyons  
Tel: 781-826-4551  
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Preparation date: April 19, 2011

**2. Device Name/ Classification: Stratus® CS Acute Care™ D-Dimer assay**

**Class:** Fibrinogen and Fibrin Split Product, Antigen, Antiserum  
and controls, Class II  
21 CFR 864.7320  
**Panel:** Hematology (HE)  
**Product Code:** DAP

**3. Identification of the Legally Marketed Device:**

Innovance D-Dimer – K093626

**4. Device Description:**

The Stratus® CS Acute Care™ D-Dimer 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 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 D-dimer 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 STAT Fluorometric Analyzer (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 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.

**5. Device Intended Use:**

The Stratus® CS Acute Care™ D-dimer assay (DDMR) is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma on the Stratus® CS analyzer. The Stratus® CS Acute Care™ DDMR assay is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease and as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. This assay is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings

**6. Medical device to which equivalence is claimed and comparison information:**

The Stratus® CS DDMR assay is substantially equivalent to the Innovance D-Dimer (K093626) assay. The Stratus® CS DDMR method, like the Innovance D-Dimer method, is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease.

**7. Device Performance Characteristics:**

**Clinical Performance of the Stratus® CS Acute Care™ D-Dimer assay to exclude PE in Citrated Plasma**

The Stratus® CS Acute Care™ D-Dimer assay was evaluated on the Stratus® CS analyzer in a multi-center study to validate the exclusion of PE using fresh citrated plasma specimens collected from 730 consecutive patients presenting to the emergency department with suspected PE. Of these 730 patients, 75 were excluded for a total of 655 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a high, moderate or low pretest probability (PTP) of PE. Patient specimens were tested with the Stratus® CS Acute Care™ D-Dimer assay and results were compared to a cutoff value of 450 ng/mL [ $\mu\text{g/L}$ ] (FEU). A D-dimer result  $<450$  ng/mL [ $\mu\text{g/L}$ ] (FEU) was considered negative and a D-dimer result  $\geq 450$  ng/mL [ $\mu\text{g/L}$ ] (FEU) was considered positive.

Patients with a positive D-dimer result and/or a high PTP were evaluated by imaging methods, e.g. spiral CT and/or VQ scan. Patients with a negative D-dimer result and a low or moderate PTP (these patients underwent imaging at the physician's discretion), and patients with negative imaging results, were followed for three months to evaluate potential development of PE.

The overall prevalence of PE in those patients available for final analysis was 14.0% (92/655). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95% confidence limits (CL) were obtained with the Stratus® CS Acute Care™ D-Dimer clinical cutoff of 450 ng/mL [ $\mu\text{g/L}$ ] (FEU).

**Citrated Plasma: In all patients**

Instrument	PE Patients (n)	Cutoff ng/mL [ $\mu$ g/L] FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
Stratus® CS analyzer	655	450	98.9 (94.1 – 100.0)	42.5 (38.3 – 46.7)	99.6 (97.7 – 100.0)

**Citrated Plasma: In Patients with low and moderate pre-test probability**

Instrument	PE Patients (n)	Cutoff ng/mL [ $\mu$ g/L] FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
Stratus® CS analyzer	625	450	98.7 (92.9 – 100.0)	43.0 (38.8 – 47.3)	99.6 (97.7 – 100.0)

**Clinical Performance of the Stratus® CS Acute Care™ D-Dimer assay to exclude PE in Heparinized Plasma**

The Stratus® CS Acute Care™ D-Dimer assay was evaluated on the Stratus® CS analyzer in a multi-center study to validate the exclusion of PE using fresh heparinized plasma specimens collected from 468 consecutive patients presenting to the emergency department with suspected PE. Of these 468 patients, 41 were excluded for a total of 427 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a high, moderate or low pre-test probability (PTP) of PE. Patient specimens were tested with the Stratus® CS Acute Care™ D-Dimer assay and results were compared to a cutoff value of 450 ng/mL [ $\mu$ g/L] (FEU). A D-dimer result <450 ng/mL [ $\mu$ g/L] (FEU) was considered negative and a D-dimer result  $\geq$ 450 ng/mL [ $\mu$ g/L] (FEU) was considered positive.

Patients with a positive D-dimer result and/or a high PTP were evaluated by imaging methods, e.g. spiral CT and/or VQ scan. Patients with a negative D-dimer result and a low or moderate PTP (these patients underwent imaging at the physician's discretion), and patients with negative imaging results, were followed for three months to evaluate potential development of PE.

The overall prevalence of PE in those patients available for final analysis was 14.1% (60/427). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95% confidence limits (CL) were obtained with the Stratus® CS Acute Care™ D-Dimer clinical cutoff of 450 ng/mL [ $\mu$ g/L] (FEU).

**Heparinized Plasma: In all patients**

Instrument	PE Patients (n)	Cutoff ng/mL [ $\mu$ g/L] FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
Stratus® CS analyzer	427	450	98.3 (91.1 – 100.0)	29.7 (25.1 – 34.7)	99.1 (95.0* – 100.0)

\*95.04

**Heparinized Plasma: in Patients with low and moderate pre-test probability**

Instrument	PE Patients (n)	Cutoff ng/mL [ $\mu$ g/L] FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
Stratus® CS analyzer	401	450	97.9 (88.7 – 100.0)	29.9 (25.2 – 35.0)	99.1 (94.9 – 100.0)

<b>Comparative Method</b>	<b>Slope</b>	<b>Intercept (ng/mL) [<math>\mu</math>g/L] FEU</b>	<b>Correlation Coefficient</b>	<b>n</b>
INNOVANCE® D-Dimer	0.950	-12.32	0.938	396

The range of samples: 54 to 4506 ng/mL [ $\mu$ g/L] FEU

**8. Conclusion:**

These studies demonstrate correlation and equivalent performance between the Innovance® D-Dimer assay and the Stratus® CS Acute Care™ D-Dimer assay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

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10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics  
c/o Ms. Kathleen Ann Dray-Lyons  
Manager, Regulatory Affairs  
500 GBC Drive  
P.O. Box 6101  
Newark, DE 19714-6101

**MAY 16 2011**

Re: k110303

Trade/Device Name: Stratus CS<sup>®</sup> Acute Care<sup>™</sup> DDMR  
Regulation Number: 21 CFR 864.7320  
Regulation Name: Fibrinogen/Fibrin Degradation Products Assay  
Regulatory Class: Class II  
Product Code: DAP  
Dated: April 20, 2011  
Received: April 21, 2011

Dear Ms. Dray-Lyons:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

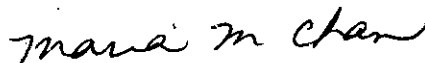
Page 2 -- Ms. Kathleen Ann Dray-Lyons

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Maria M. Chan, Ph.D.  
Director  
Division of Immunology and Hematology Devices  
Office of *In Vitro* Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K110303

Device Name: Stratus® CS Acute Care™ DDMR

### Indications For Use:

The Stratus® CS Acute Care™ D-dimer assay (DDMR) is an *in vitro* diagnostic test for the quantitative measurement of cross-linked fibrin degradation products (D-dimer) in human citrated or heparinized plasma on the Stratus® CS analyzer. The Stratus® CS Acute Care™ DDMR assay is intended for use in conjunction with a non-high clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) disease and as an aid in the diagnosis of venous thromboembolism (VTE) [deep vein thrombosis (DVT) or pulmonary embolism (PE)]. This assay is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

Prescription Use   X   AND/OR Over-The-Counter-Use         
(Per 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 Device Evaluation

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Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

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