MAY - 4 2006

# 510(k) Summary for Stratus® CS Acute™ Care *Cardio*Phase® hsCRP

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: K060369

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

Manufacturer:
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714

Contact Information:
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, Delaware 19714
Attn: Kathleen Dray-Lyons
Tel: 781-826-4551
Fax: 781-826-2497

Preparation date: February 10, 2006

**2. Device Name:**
Stratus® CS Acute Care™ *Cardio*Phase® hsCRP TestPak
Stratus® CS Acute Care™ *Cardio*Phase® hsCRP CalPak
Stratus® CS Acute Care™ *Cardio*Phase® hsCRP DilPak

**Classification:** Class II
21 CFR 866.5270; 862.1150
**Panel:** Immunology (81)
**Product Code:** NQD; JIT

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

Dade Behring *Cardio*Phase hsCRP– K033908

## 4. Device Description:

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP method is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology.

## 5. Device Intended Use:

**Stratus® CS Acute Care™ *Cardio*Phase® hsCRP TestPak:**
The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP assay is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in lithium and sodium heparin plasma. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, is observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. High sensitivity CRP (hsCRP) measurements may be used as an independent risk marker for the identification of individuals at risk for future cardiovascular disease. Measurements of hsCRP, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes.

**Stratus® CS Acute Care™ *Cardio*Phase® hsCRP CalPak:**
The Stratus® CS Acute Care™ *Cardio*Phase® high sensitivity CRP Calibrator, is an *in vitro* diagnostic product intended to be used for calibration of the Acute Care™ *Cardio*Phase® method on the Stratus® CS analyzer.

**Stratus® CS Acute Care™ *Cardio*Phase® hsCRP DilPak:**

The Stratus® CS Acute Care™ *Cardio*Phase® high sensitivity CRP Dilution Pak, is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ *Cardio*Phase® TestPak, for the measurement of samples with elevated levels of C-reactive protein.

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

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP assay is substantially equivalent to the Dade Behring *Cardio*Phase® hsCRP assay (K033908). The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP assay, like the Dade Behring *Cardio*Phase® hsCRP assay is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein (CRP).

## 7. Device Performance Characteristics:

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP assay was compared to the Dade Behring *Cardio*Phase® hsCRP assay by evaluating 154 plasma samples with concentrations ranging from 0.20 to 48.05 mg/L. Regression analysis of the results yielded the following equations:

**Method Comparison Study**

| Comparative Method | Range of Sample values | Slope | Intercept | Correlation Coefficient | N |
|---|---|---|---|---|---|
| Dade Behring *Cardio*Phase® hsCRP, performed on the BN™ System | 0 – 50 mg/L | 0.952 | 0.098 | 0.999 | 154 |
| | 0 – 10 mg/L | 0.997 | 0.047 | 0.995 | 123 |
| | 0 – 5 mg/L | 1.002 | 0.042 | 0.994 | 107 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kathleen Dray-Lyons
Manager, Regulatory Affairs and Compliance
Dade Behring Inc.
Glasgow Building 500
PO Box 6101, M/S 514
Newark DE 19714

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Re: k060369
Trade/Device Name: Stratus® CS Acute Cute™ *Cardio*Phase® hsCRP TestPak
Stratus® CS Acute Cute™ *Cardio*Phase® hsCRP CalPak
Stratus® CS Acute Cute™ *Cardio*Phase® hsCRP DilPak
Regulation Number: 21 CFR§ 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: NQD, JIT
Dated: February 10, 2006
Received: February 13, 2006

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 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 Statement

**Device Name:** **Stratus® CS Acute Care™ *Cardio*Phase® hsCRP**

## Indications for Use:

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Prescription Use X
(Per 21 CFR 801 Subpart D)

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 C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(510(k)) K060369