DEC 26 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: K062924

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:	September 27, 2006

2. Device Name / Classification

- Stratus® CS Acute Care™ *Cardio*Phase® hsCRP TestPak / Class II

3. Identification of the Predicate Device

- Dade Behring Stratus® CS Acute Care™ *Cardio*Phase® hsCRP TestPak K060369

4. Device Description(s):

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:

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP method is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in lithium and sodium heparin plasma. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

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.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:

The product is substantially equivalent to the commercial Dade Behring Stratus® CS CardioPhase® hsCRP TestPak: K060369

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS CardioPhase® hsCRP TestPak (K060369). Both assays are *in vitro* diagnostic tests for the quantitative measurement of the C-reactive protein (CRP) in lithium and sodium heparin plasma and are useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

There are no formulation or design changes associated with the Stratus® CS CardioPhase® hsCRP TestPak indications for use change. The two products are identical and use the same manufacturing processes. Labeling changes reflect the new indications for use and include supporting data.

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.

Comparison to Predicate Device:

The modification of this method by adding point of care to the indications for use is supported by data included in Section 18.

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

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

Conclusion:

The product listed in the following table is substantially equivalent based on its 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 CardioPhase® hsCRP TestPak (K060369)	Stratus® CS Acute Care™ CardioPhase® hsCRP TestPak

Pamela A. Jurga
Regulatory Affairs and Compliance Manager
September 27, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Pamela A. Jurga
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

DEC 26 2006

Re: k062924
Trade/Device Name: Stratus CS Acute Care CardioPhase hsCRP TestPak
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Product Code: NQD
Dated: September 27, 2006
Received: September 28, 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) 276-0490. 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

510(k) Number (if known): K062924

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

Indications For Use:

The Stratus® CS Acute Care™ *Cardio*Phase® hsCRP method is an *in vitro* diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in lithium and sodium heparin plasma. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

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.

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)

Dean Cooper, M.S., DVM
Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety
510(k) K062924