

SEP -- 8 2005

K 051650

**C SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

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.

**Submitter's Name:** Pamela A. Jurga  
Dade Behring Inc.  
P.O. Box 6101  
Newark, DE 19714-6101  
302-631-8891

**Date of Preparation:** June 6, 2005

**Name of Product(s):** Stratus® CS Acute Care™ MB isoenzyme of creatine kinase (CKMB) TestPak  
Stratus® CS Acute Care™ CKMB CalPak (the assay calibrator)  
Stratus® CS Acute Care™ CKMB DilPak (the assay diluent)  
Stratus® CS Acute Care™ Troponin I (cTnI) TestPak  
Stratus® CS Acute Care™ cTnI CalPak (the assay calibrator)  
Stratus® CS Acute Care™ cTnI DilPak (the assay diluent)  
Stratus® CS Acute Care™ Myoglobin (MYO) TestPak  
Stratus® CS Acute Care™ MYO CalPak (the assay calibrator)  
Stratus® CS Acute Care™ MYO DilPak (the assay diluent)

**FDA Classification Name(s):**

- Fluorometric method, cpk or isoenzymes and associated calibrator and diluent
- Immunoassay method, troponin subunit and associated calibrator and diluent
- Myoglobin, Antigen, Antiserum Control and associated calibrator and diluent (all Class II)

**FDA Guidance Document(s):** "Bundling Multiple Devices or Multiple Indications in a Single Submission"  
- 11/26/2003

**Predicate Device(s):**

- Dade Behring Stratus® STAT Fluorometric Analyzer CKMB TestPak including DilPak (K984067/K981099) and Stratus® CS CKMB CalPak (K981097)  
(Note: This submission included the Stratus® CS STAT Fluorometric Analyzer in addition to the CKMB TestPak and DilPak)
- Dade Behring Stratus® CS Acute Care™ Troponin I (cTnI) TestPak including DilPak (K033487/K984093/K981098) and Stratus® CS cTnI CalPak (K012233/K983722/K012233)
- Dade Behring Stratus® CS STAT Fluorometric Analyzer MYO TestPak including DilPak (K981102/K984065) and Stratus® CS MYO CalPak (K981101)

## Device Description(s):

### **CKMB**

#### **Method**

The Stratus® CS Acute Care™ CKMB method is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal CKMB antibody is added to the center portion of a square piece of glass fiber paper in the CKMB TestPak. Sample is then added onto the paper where it reacts with the immobilized anti-CKMB antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against a distinct antigenic site on the B subunit of the CKMB molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound CKMB, 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 CKMB in the sample. The reaction rate 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 CKMB calibrator (CKMB CalPak) is a refrigerated liquid product containing human heart CKMB in a buffered bovine protein 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 CKMB Diluent (CKMB DilPak) is a refrigerated liquid product containing buffered human protein matrix with stabilizers and 0.2% sodium azide. The kit consists of 5 DilPaks with diluent in one well.

### **cTnI (TROP on original submission)**

#### **Method**

The Stratus® CS Acute Care™ Troponin I 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 cTnI TestPak. This antibody recognizes a distinct antigenic site on the cardiac troponin I 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 cardiac troponin I molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound cardiac troponin I, 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 cardiac troponin I 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 Troponin I calibrator (cTnI CalPak) is a frozen liquid product containing native, human troponin complex, in a human serum base with less than 0.1% sodium azide. 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 Troponin I Diluent (cTnI DilPak) is a refrigerated liquid product containing phosphate buffer with preservatives including less than 0.1% sodium azide. The kit consists of 5 DilPaks with diluent in one well.

### MYO

#### Method

The Stratus® CS Acute Care™ MYO method is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. In this procedure, dendrimer linked monoclonal myoglobin antibody is added to the center portion of a square piece of glass fiber paper in the MYO TestPak. This antibody recognizes a distinct antigenic site on the myoglobin molecule. Sample is then added onto the paper where it reacts with the immobilized anti-myoglobin antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against a distinct antigenic site on the myoglobin molecule is pipetted onto the reaction zone of the paper. During this second incubation period, enzyme-labeled antibody reacts with the bound myoglobin, 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 myoglobin 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 MYO calibrator (MYO CalPak) is a refrigerated liquid product containing human heart myoglobin in a bovine albumin matrix with stabilizers and less than 0.1 % sodium azide. 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 MYO Diluent (MYO DilPak) is a refrigerated liquid product containing a buffered bovine protein matrix with stabilizers and 0.2 % sodium azide. The kit consists of 5 DilPaks with diluent in one well.

### **Intended Use:**

### CKMB

#### Method

The Stratus® CS Acute Care™ CKMB method is an *in vitro* diagnostic test for the measurement of the MB isoenzyme of creatine kinase (ATP: Creatine N-Phosphotransferase, E. C. No. 2.7.3.2) in heparinized plasma. CKMB measurements can be used as an aid in diagnosing acute myocardial

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

#### Diluent

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

#### **cTnI**

##### Method

The Stratus® CS Acute Care™ Troponin I (cTnI) method is an *in vitro* diagnostic test for the measurement of cardiac troponin I in heparinized plasma. Cardiac troponin I measurements can be used as an aid in the diagnosis of acute myocardial infarction (AMI). Cardiac troponin I can also be used as aid in the risk stratification of patients with acute coronary syndromes (ACS) with respect to their relative risk of mortality. 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™ Troponin I Calibrator (cTnI CalPak), CAT. NO. CCTNI-C, is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ cardiac troponin I method.

#### Diluent

The Stratus® CS Acute Care™ Troponin I Dilution Pak (cTnI DilPak), CAT. NO. CCTNI-D, is an *in vitro* diagnostic product intended to be used in conjunction with the Acute Care™ cTnI TestPak, CAT. NO. CCTNI, for the measurement of samples with elevated levels of cardiac troponin I.

#### **MYO**

##### Method

The Stratus® CS Acute Care™ myoglobin (MYO) method is an *in vitro* diagnostic test for the measurement of the myoglobin in heparized plasma. Myoglobin measurements can be used as an aid in diagnosing myocardial infarction. 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™ Myoglobin Calibrator (MYO CalPak), CAT. NO. CMYO-C, is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ Myoglobin method.

#### Diluent

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

## **Substantial Equivalence:**

### **CKMB**

#### **Method**

The Stratus® CS Acute Care™ CKMB Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS CKMB TestPak (K984067/K981099). Both assays are in vitro immunoassays with an intended use as an aid in diagnosing acute myocardial infarction.

There are no formulation or design changes associated with the Stratus® CS CKMB 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™ CKMB calibrator (CKMB CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS CKMB CalPak (K981097). Both calibrators are intended to be used to calibrate the Stratus® CS Acute Care™ CKMB assay.

There are no formulation or design changes associated with the Stratus® CS CKMB TestPak intended use 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™ CKMB Dil Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS CKMB DilPak (K984067/K981099). Both diluents are intended to be used in conjunction with the Stratus® CS Acute Care™ CKMB TestPaks for the measurement of samples with elevated levels of CKMB.

There are no formulation or design changes associated with the Stratus® CS CKMB TestPak intended use 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.

### **cTnI**

#### **Method**

The Stratus® CS Acute Care™ Troponin I Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus CS Acute Care™ Troponin I TestPak (K033487/K984093/K981098). Both assays are in vitro immunoassays with an intended use as an aid in the diagnosis of acute myocardial infarction and risk stratification of patients with acute coronary syndrome.

There are no formulation or design changes associated with the Stratus® CS cTnI 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™ Troponin I Calibrator (cTnI CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus CS Acute Care™ Troponin I CalPak (K012233/K983722/K981100). Both calibrators are intended to be used to calibrate the Troponin I (cTnI) assay on the Stratus® CS analyzer.

There are no formulation or design changes associated with the Stratus® CS Acute Care™ cTnI TestPak intended use 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.

There are no formulation or design changes associated with the Stratus® CS CKMB TestPak intended use 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™ Troponin I Dil Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS cTnI DilPak (K981098). Both diluents are intended to be used in conjunction with the cTnI TestPak on the Stratus® CS analyzer for the measurement of samples with elevated levels of cardiac troponin I.

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.

#### **MYO**

##### Method

The Stratus® CS Acute Care™ MYO Test Pak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS MYO TestPak (K981102/K984065). Both assays are in vitro immunoassays with an intended use as an aid in diagnosing acute myocardial infarction.

There are no formulation or design changes associated with the Stratus® CS MYO 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™ Myoglobin Calibrator (MYO CalPak) is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS MYO CalPak

(K981101). Both calibrators are intended to be used for calibration of the Stratus® CS Acute Care™ MYO method.

There are no formulation or design changes associated with the Stratus® CS MYO TestPak intended use 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™ MYO DilPak is substantially equivalent in the principle of operation and performance to the current Dade Behring Stratus® CS MYO DilPak (K984065/K981102). Both diluents are intended to be used in conjunction with the MYO TestPak on the Stratus® CS analyzer for the measurement of samples with elevated levels of myoglobin.

There are no formulation or design changes associated with the Stratus® CS MYO TestPak intended use 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:**

The modification of these three methods by adding point of care to the intended use is supported by data submitted in their original method 510(k)'s included in Attachment D.

Method comparison and precision analysis were performed at three different locations (clinical laboratory (LAB), Emergency Department (ED) and Cardiac Care Unit (CCU) within each of two 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 the original 510(k)'s.

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.

<b>Predicate Device</b>	<b>New Device</b>
Dade Behring Stratus® STAT Fluorometric Analyzer CKMB TestPak (K984067/K981099)	The Stratus® CS Acute Care™ MB isoenzyme of creatine kinase (CKMB) TestPak
Stratus® CS CKMB CalPak (K981097)	Stratus® CS Acute Care™ CKMB CalPak
Stratus® CS CKMB DilPak (K984067/K981099)	Stratus® CS Acute Care™ CKMB DilPak
Dade Behring Stratus® CS Acute Care™ Troponin I (cTnI) TestPak (K033487/K984093/K981098)	Stratus® CS Acute Care™ Troponin I (cTnI) TestPak

Stratus® CS cTnI CalPak (K012233/K983722/K012233),	Stratus® CS Acute Care™ cTnI CalPak
Stratus® CS cTnI DilPak (K033487/K984093/K981098)	Stratus® CS Acute Care™ cTnI DilPak
Dade Behring Stratus® CS STAT Fluorometric Analyzer MYO TestPak (K981102/K984065)	Stratus® CS Acute Care™ Myoglobin (MYO) TestPak
Stratus® CS MYO CalPak (K981101)	Stratus® CS Acute Care™ MYO CalPak
Stratus® CS MYO DilPak (K981102/K984065)	Stratus® CS Acute Care™ MYO DilPak

Pamela A. Jurga  
Regulatory Affairs and Compliance Manager  
June 16, 2005





SEP - 8 2005

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 19714-6101

Re: k051650  
Trade/Device Name: Stratus® CS Acute Care™ MB isoenzyme of creatine kinase  
(CKMB) TestPak  
Stratus® CS Acute Care™ CKMB CalPak  
Stratus® CS Acute Care™ CKMB DilPak  
Stratus® CS Acute Care™ Troponin I (cTnI) TestPak  
Stratus® CS Acute Care™ cTnI CalPak  
Stratus® CS Acute Care™ cTnI DilPak  
Stratus® CS Acute Care™ Myoglobin (MYO) TestPak  
Stratus® CS Acute Care™ MYO CalPak  
Stratus® CS Acute Care™ MYO DilPak

Regulation Number: 21 CFR 862.1215  
Regulation Name: Creatine phosphokinase/creatin kinase or isoenzymes test system  
Regulatory Class: Class II  
Product Code: JHX, MMI, DDR, JIT  
Dated: June 16, 2005  
Received: June 21, 2005

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.

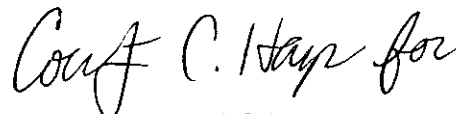
Page 2 – Ms. Jurga

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,



Carol C. Benson, M.A.  
Acting 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 STATEMENTS.**

**INDICATIONS FOR USE STATEMENT**

510(k) Number (If Known): K051650

**Device(s) Name(s):**

Stratus® CS Acute Care™ MB isoenzyme of creatine kinase (CKMB) TestPak  
Stratus® CS Acute Care™ CKMB CalPak  
Stratus® CS Acute Care™ CKMB DilPak

**Indications for Use:**

The Stratus® CS Acute Care™ CKMB method is an *in vitro* diagnostic test for the measurement of the MB isoenzyme of creatine kinase (ATP: Creatine N-Phosphotransferase, E.C. No 2.7.3.2) in heparinized plasma. Measurements of CKMB are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy. This method is for use by trained health care professionals in the clinical laboratory and point of care (POC) settings.

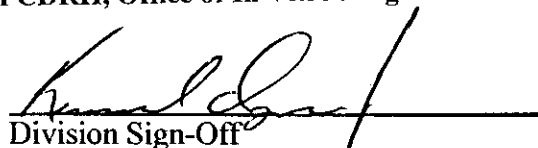
The Stratus® CS Acute Care™ CKMB Calibrator (CKMB CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ CKMB method.

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

Prescription Use X and/or Over-the-counter Use  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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) 051650

## INDICATIONS FOR USE STATEMENT

510(k) Number (If Known): K 0 5 1 6 5 0

### Device(s) Name(s):

Stratus® CS Acute Care™ Troponin I (cTnI) TestPak  
Stratus® CS Acute Care™ cTnI CalPak  
Stratus® CS Acute Care™ cTnI DilPak

### Indications for Use:

The Stratus® CS Acute Care™ Troponin I method (cTnI) is an *in vitro* diagnostic assay for the measurement of cardiac troponin I in heparinized plasma. Cardiac troponin I measurements can be used as an aid in the diagnosis of acute myocardial infarction (AMI). Cardiac troponin I can also be used as an aid in the risk stratification of patients with acute coronary syndromes (ACS) with respect to their relative risk of mortality. 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™ Troponin I Calibrator (cTnI CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ Troponin I method.

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

Prescription Use X

and/or

Over-the-counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

[Signature]  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) 051650

INDICATIONS FOR USE STATEMENT

510(k) Number (If Known): K 051650

Device(s) Name(s):

Stratus® CS Acute Care™ Myoglobin (MYO) TestPak  
Stratus® CS Acute Care™ MYO CalPak  
Stratus® CS Acute Care™ MYO DilPak

Indications for Use:

The Stratus® CS Acute Care™ Myoglobin method (MYO) is an *in vitro* diagnostic assay for the measurement of myoglobin in heparinized plasma. Measurements of myoglobin aid in the rapid diagnosis of renal or heart disease, e.g. myocardial infarction. 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™ Myoglobin Calibrator (MYO CalPak) is an *in vitro* diagnostic product intended to be used for calibration of the Stratus® CS Acute Care™ myoglobin method.

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

Prescription Use   X  

and/or

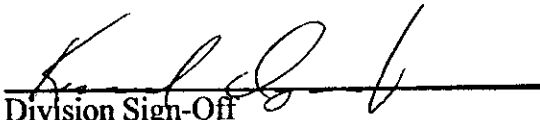
Over-the-counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(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) K 051650