

DEC 14 1998

K984065

# DADE BEHRING

DADE BEHRING INC.  
P.O. Box 6101  
Newark, DE 19714

## 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:** Rebecca S. Ayash  
Dade Behring Inc.  
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P.O. Box 6101  
Newark, DE 19714-6101

**Date of Preparation:** 11/6/98

**Device Name:** Stratus® CS Myoglobin (MYO) TestPak

**Classification Name:** Myoglobin Immunological Test System

**Predicate Device:** Stratus® CS Myoglobin (MYO) TestPak (K981102)

**Device Description:** The MYO TestPak consists of a plastic cartridge with five wells and a small square of glass fiber paper embedded in it. The method utilizes 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 MYO TestPak. 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 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 of the TestPak. 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 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.

This device was previously cleared under K981102. Subsequently, the product insert has been modified to change the recommended frequency of quality control from daily to weekly.

**Intended Use:** The Myoglobin (MYO) TestPak used on the Stratus® CS STAT Fluorometric Analyzer is an *in vitro* diagnostic product for the measurement of myoglobin in heparinized plasma. Measurements of myoglobin are used as aids in the rapid diagnosis of renal and heart disease, e.g. acute myocardial infarction.

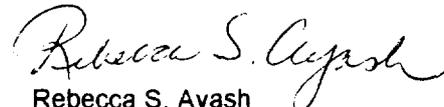
**Comparison to Predicate Device:**

Feature	Stratus CS® MYO (modified)	Stratus CS® MYO (K981102)
Principle of procedure	Two-site sandwich assay	Two-site sandwich assay
Type of measurement	Fluorometric	Fluorometric
Solid Phase	Glass fiber paper	Glass fiber paper
Sample Type	Heparinized plasma	Heparinized plasma
Recommended QC Frequency	At least once each week	At least daily
Intended Use	For the quantitative measurement of myoglobin	For the quantitative measurement of myoglobin
Indications for Use	For use as an aid in the rapid diagnosis of renal and heart disease, e.g. acute myocardial infarction	For use as an aid in the rapid diagnosis of renal and heart disease, e.g. acute myocardial infarction

**Comments on Substantial**

**Equivalence:** Both assays are *in vitro* immunoassays with intended uses for the measurement of Myoglobin in heparinized plasma. The modified device differs from the device cleared under K981102 only in the recommended QC frequency in product labeling.

**Conclusion:** The QC data collected supports the recommended change in QC frequency and indicates the change will not adversely affect performance of the device.



Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 11/13/98



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Ms. Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Dade Behring  
Building 500, Mailbox 514  
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Newark, Delaware 19714-6101

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: K984065  
Trade Name: Stratus® CS Myoglobin (MYO) TestPak  
Regulatory Class: II  
Product Code: DDR  
Dated: November 13, 1998  
Received: November 16, 1998

Dear Ms. Ayash:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

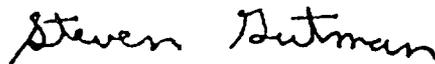
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications Statement

**Device Name:** Stratus® CS Myoglobin (MYO) TestPak

**Indications for Use:** The MYO TestPak used on the Stratus® CS STAT Fluorometric Analyzer is an *in vitro* diagnostic product for the measurement of Myoglobin in heparinized plasma. Measurements of Myoglobin are used as aids in the rapid diagnosis of renal or heart disease, e.g. acute myocardial infarction.

*Rebecca S. Ayash*

Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 11/13/98

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K984065  
510(k) Number

\_\_\_\_\_  
Division Sign-Off  
Office of Device Evaluation

prescription use

*[Signature]*  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Sciences  
510(k) Number K984065