JAN 1 3 1999

K984067

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. Building 500, Mailbox 514 P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	11/13/98
Device Name:	Stratus® CS STAT Fluorometric Analyzer Stratus® CS CKMB TestPak
Classification Name:	Fluorometer, for Clinical Use Fluorometric Method, CPK or Isoenzymes
Predicate Device:	Stratus® CS STAT Fluorometric Analyzer (K981099) Stratus® CS CKMB TestPak (K981099)

Device Description: The Stratus® CS STAT Fluorometric Analyzer is a benchtop analyzer capable of processing up to four *in vitro* diagnostic tests per sample. An operator of the analyzer introduces a specimen collection tube filled with whole blood into the analyzer, along with the appropriate TestPaks for processing. The analyzer transfers and spins an aliquot of the sample, delivers the spun plasma and other self-contained reagents to the reaction area of the TestPak, reads the reaction rate via front surface fluorescence and prints out quantitative test results.

The CKMB 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 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 antibody directed against a distinct antigenic site of the B subunit on 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 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 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.

These devices were previously cleared under K981099. Subsequently, the labeling of the TestPak and the analyzer software and Operator's Guide have been modified to change the recommended frequency of quality control from daily to weekly.

Intended Use: The Stratus® CS STAT Fluorometric Analyzer is a microprocessor-controlled instrument that measures analytes in body fluid for *in vitro* diagnostic use.

The CKMB TestPak used on the Stratus® CS STAT Fluorometric Analyzer is an *in vitro* diagnostic product for the measurement of the MB isoenzyme of creatine kinase in heparinized plasma. Measurements of CKMB can be used as an aid in the diagnosing of acute myocardial infarction.

Comparison to Predicate Device: The Stratus® CS STAT Fluorometric Analyzer and Stratus®CS CKMB TestPak differ from the devices cleared under K981099 only in the allowed QC frequency in analyzer software and the QC frequency recommendation in corresponding labeling. All other features of these devices are the same.

Comments on Substantial Equivalence: Both the analyzer and the CKMB TestPak have the same intended uses as the devices cleared under K981099. The modified devices are the same other than software and labeling changes to accommodate a recommended change in QC frequency.

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

Rebecca S. Ayash

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 1999

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

Re: K984067
Trade Name: Stratus® CS STAT Fluorometric Analyzer, Stratus® CS CKMB TestPak
Regulatory Class: II
Product Code: JHX
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 (Premarket 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 Gutman

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 STAT Fluorometric Analyzer

Indications for Use: The Stratus® CS STAT Fluorometric Analyzer is intended to duplicate manual analytical procedures by performing automatically various steps, such as pipetting, incubation and measuring fluorescence.

Device Name: Stratus® CS CKMB TestPak

Indications for Use: Measurements of CKMB are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K984067
510(k) Number

Division Sign-Off
Office of Device Evaluation

✓ prescription use