

MAY

K981099

MAY 26 1998

SECTION A

Summary of Safety and Effectiveness

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DADE BEHRING

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

Stratus® CS STAT fluorometric analyzer Stratus® CS CKMB TestPak

Summary of Safety and Effectiveness

The Stratus® CS STAT fluorometric analyzer is a benchtop instrument 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 instrument, along with the appropriate TestPaks for processing. The instrument 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 used on the Stratus® CS STAT fluorometric analyzer is an *in vitro* diagnostic test for the measurement of the MB isoenzyme of creatine kinase in heparinized plasma.

The Stratus® CS STAT fluorometric analyzer is substantially equivalent to the Dade Stratus® fluorometric analyzer, which was cleared by the FDA through the 510(k) process. The CKMB assay performed by the CKMB TestPak is substantially equivalent to the CKMB assay performed on the Dade Stratus® analyzer, which was also cleared by the FDA through the 510(k) process. Both methodologies have the same intended uses and are processed on automated systems using similar detection systems for the determination of CKMB.

A split sample comparison study was conducted between the two systems with the following results:

<u>n</u>	<u>Slope</u>	<u>Intercept</u>	<u>Correlation Coefficient</u>	<u>Range of Samples</u>
215	0.97	0.65	0.988	0.0 - 123.9 ng/mL

Carolyn K. George
Carolyn K. George
Regulatory Affairs and
Compliance Manager

March 24, 1998
Date



MAY 26 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Carolyn K. George
• Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, Delaware 19714

Re: K981099
Stratus® CS STAT Fluorometric Analyzer and Stratus® CS
CKMB TestPak
Regulatory Class: II
Product Code: JHX, KHO
Dated: March 24, 1998
Received: March 26, 1998

Dear Ms. George:

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 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.

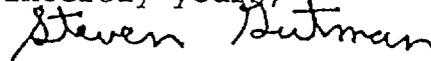
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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 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.

Device Name: Stratus® CS STAT fluorometric analyzer

Indications for Use: The fluorometric analyzer is intended to duplicate manual analytical procedures by performing automatically various steps, such as pipetting, incubation and measuring fluorescence.

Carolyn K. George

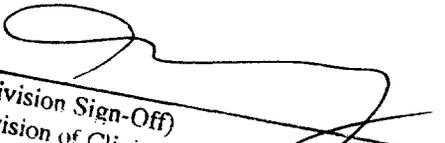
**Carolyn K. George
Regulatory Affairs and
Compliance Manager**

March 24, 1998

Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K2 981099

K981099
510(k) Number

Division Sign-Off
Office of Device Evaluation

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prescription use

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