K981102

DADE BEHRING

APR 27 1998

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 MYO TestPak

Summary of Safety and Effectiveness

The MYO TestPak used on the Stratus® CS STAT fluorometric analyzer is an *in vitro* diagnostic test for the measurement of myoglobin.

This myoglobin assay is a two-site sandwich assay based upon solid phase Radial Partition Immunoassay (RPIA) technology. 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.

The myoglobin assay performed with the MYO TestPak is substantially equivalent to the myoglobin assay performed on the Dade Stratus® analyzer, which was cleared by the FDA through the 510(k) process. Both methodologies have the same intended uses and are processed on automated systems which use a fluorescence detection for the determination of myoglobin.

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

n	Slope	Intercept	Correlation Coefficient	Range of Samples
203	0.97	8	0.987	15 - 829 ng/mL

Carolyn K. George

Carolyn K. George
Regulatory Affairs and
Compliance Manager

March 25, 1998

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 27 1998

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

Re: K981102
Stratus® CS Myoglobin (MYO) TestPak
Regulatory Class: II
Product Code: DDR
Dated: March 25, 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.

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 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 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.

Carolyn K. George

Carolyn K. George
Regulatory Affairs and
Compliance Manager

March 25, 1998

Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K981102

510(k) Number

Division Sign-Off
Office of Device Evaluation

✓ prescription use