K972782
Aug 15, 1997

DADE

DADE INTERNATIONAL

Chemistry Systems
P.O. Box 6101
Newark, DE 19714

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® CK-MB Fluorometric Enzyme Immunoassay

Summary of Safety and Effectiveness

The Dade Stratus® CK-MB Fluorometric Enzyme Immunoassay is an *in vitro* diagnostic test for the MB isoenzyme of creatine kinase. The assay can be processed on the Stratus® analyzer, the Stratus® II analyzer or the Stratus® IIntellect analyzer.

The Stratus® CK-MB Fluorometric Enzyme Immunoassay has been cleared by the Food and Drug Administration, via its 510(k) process, for use with human serum samples. This submission supports expansion of the sample type to include human heparinized plasma samples. There have been no modifications in configuration or formulation to the Stratus® CK-MB Fluorometric Enzyme Immunoassay.

A comparison study between serum and heparinized plasma samples was conducted with the following results:

	Slope	Intercept	Correlation Coefficient	Range of Samples
Serum/Plasma (n = 169 sets)	1.17	1.6	0.976	0 - 113.1 ng/mL

Carolyn K. George

Carolyn K. George
Regulatory Affairs and
Compliance Manager

July 23, 1997

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carolyn K. George
Regulatory Affairs and
Compliance Manager
Dade International
Post Office Box 6101
Newark, DE 19714

AUG 15 1997

Re: K972782
Stratus® CK-MB Fluorometric Enzyme Immunoassay
Regulatory Class: II
Product Code: JHX
Dated: July 24, 1997
Received: July 25, 1997

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 requirement, 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

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Indications Statement

Device Name: Stratus® CK-MB Fluorometric Enzyme Immunoassay

Indications for Use: Measurements of creatine kinase MB isoenzyme are used in the diagnosis and treatment of myocardial infaction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

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

July 23, 1997
Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K972782
510(k) Number

Prescription Use ✓
(Per 21 CFR 801.109)

D Blagmon for A. Montgomery
Division Sign-Off
Office of Device Evaluation

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