

DEC 10 1998

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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:** 11/20/98

**Device Name:** Myoglobin Flex™ reagent cartridge

**Classification Name:** Myoglobin Immunological Test System

**Predicate Device:** Stratus® Myoglogobin Fluorometric Enzyme Immunoassay

**Device Description:** The MYO method for the Dimension® RxL system with the heterogeneous immunoassay module is a one-step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles (CrO<sub>2</sub>) coated with monoclonal antibodies specific for myoglobin and conjugate reagent (β-galactosidase labeled monoclonal antibodies specific for myoglobin). A particle/MYO/conjugate sandwich forms during the incubation period. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β-galactosidase is combined with the chromogenic substrate chlorophenol red-β-d-galactopyranoside (CPRG) and catalyzes the hydrolysis of CPRG to the chromophore, chlorophenol red (CPR). The concentration of MYO present in the patient sample is directly proportional to the rate of color change measured at 577nm due to formation of CPR.

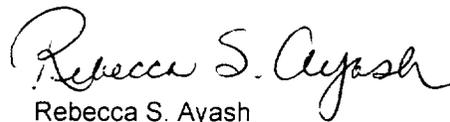
**Intended Use:** The Myoglobin (MYO) method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module is used to quantitatively measure myoglobin (MYO) in human serum and plasma as an aid in the rapid diagnosis of acute myocardial infarction.

**Comparison to Predicate Device:**

<b>Item</b>	<b>Dimension® RxL MYO</b>	<b>Stratus® Myoglobin</b>
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577 nm and 700nm	Front surface fluorometry measurement
Solid Support	Chrome	Glass fiber paper
Specimen Type	Serum or plasma	Serum or plasma
Intended Use	For the quantitative determination of myoglobin in serum and plasma	For the quantitative determination of myoglobin in serum and plasma
Indications for Use	To aid in the rapid diagnosis of acute myocardial infarction	To aid in the rapid diagnosis of acute myocardial infarction

**Comments on Substantial Equivalence:** Split sample comparison between the MYO method on the Dimension® RxL system and the Stratus® Myoglobin assay gave a correlation coefficient of 0.992, slope of 1.04, and an intercept of -4.15 ng/mL when tested with 204 clinical patient samples ranging from 10 – 1000 ng/mL.

**Conclusion:** The MYO Method for the Dimension® RxL system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the Stratus® Myoglobin assay based on the split sample comparison summarized above.



Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 11/20/98



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Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K984191  
Trade Name: Myoglobin Flex Reagent Cartridge  
Regulatory Class: II  
Product Code: DDR  
Dated: November 20, 1998  
Received: November 23, 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.

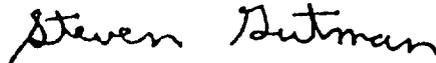
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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:** Myoglobin (MYO) Flex™ reagent cartridge

**Indications for Use:** The MYO method for the Dimension® RxL with the heterogeneous immunoassay module is a device used to quantitatively measure myoglobin in human serum and plasma as an aid in the rapid diagnosis of acute myocardial infarction.

  
Rebecca S. Ayash  
Regulatory Affairs and  
Compliance Manager  
Date: 11/20/98

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K984191  
510(k) Number  
  
Division Sign-Off  
Office of Device Evaluation

prescription use