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K991177

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
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Date of Preparation: 4/6/99

Device Name: Opus™ Troponin I (cTn) Test Modules

Classification Name: Immunoassay Method, Troponin Subunit

Predicate Device: Dimension® RxL Troponin I Flex™ Reagent Cartridge

Device Description: The Opus™ Troponin I (cTn) assay is a two-site or sandwich fluorogenic enzyme linked immunoassay. Dendrimer linked monoclonal antibody is precoated onto a piece of glass fiber paper in the cTn Test Module. This antibody recognizes a distinct antigenic site on the cardiac troponin I molecule.

The Opus™ System pipettes patient sample from a sample cup and dispenses it onto the glass fiber paper where it reacts with immobilized antibody. After a short incubation, a conjugate consisting of enzyme-labeled monoclonal antibody directed against a distinct antigenic site on the cardiac troponin I molecule is pipetted from a sealed well within the test module, onto the reaction zone of the paper. During a second incubation period, enzyme-labeled antibody reacts with the bound cardiac troponin I, forming an antibody-antigen-labeled antibody sandwich. A substrate wash solution is pipetted from a second sealed well on the test module, to the wash port. Unbound labeled antibody is eluted away from the optical read window of the Opus™ System through lateral capillary action. The substrate, 4-methylumbelliferyl phosphate is included within the wash solution allowing simultaneous substrate conversion with the wash. The enzymatic rate of the bound fraction increases directly with the concentration of cardiac troponin I in the sample. The reaction rate can then be measured by the instrument's optical system.

Intended Use: The Troponin I (cTn) assay for the Opus™ Immunoassay System is used to quantitatively measure cardiac troponin I in serum and heparinized plasma to aid in the

diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Comparison to Predicate Device:

Item	Opus™ Troponin I	Dimension® RxL Troponin I
Principle of procedure	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Monoclonal Antibodies • Tag • Capture	 • 2B1.9 • 2F6.6	 • 2B1.9 • 2F6.6
Type of measurement	Fluorogenic	Colorimetric
Solid Support	Glass fiber paper	Chromium Oxide
Specimen type	serum or heparinized plasma	serum or heparinized plasma
Sample Size	25µL	60µL
Intended Use	For the quantitative determination of cardiac troponin-I levels in serum and heparinized plasma	For the quantitative determination of cardiac troponin-I levels in serum and heparinized plasma
Indications for Use	To aid in diagnosis of myocardial infarction and to aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality	To aid in diagnosis of myocardial infarction and to aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality

Comments on Substantial Equivalence: Split sample comparison between the Opus™ cTn assay and the Dimension® RxL Troponin I assay gave a correlation coefficient of 0.9856, slope of 1.01 and an intercept of 0.1516 ng/mL when tested with 132 clinical patient samples ranging from 0.16 – 45.95 ng/mL.

Conclusion: The Opus™ Troponin assay is substantially equivalent in principle and performance to the Dimension® RxL Troponin I assay based on the split sample comparison summarized on the previous page.

Rebecca S. Ayash

Rebecca S. Ayash
Regulatory Affairs and Compliance Manager
Date: 4/6/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
DADE BEHRING INC.
Glasgow Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714

Re: K991177
Trade Name: Opus™ Troponin I (cTn) Test Modules
Regulatory Class: II
Product Code: MMI
Dated: June 15, 1999
Received: June 17, 1999

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: Opus™ Troponin I (cTn) Test Modules

Indications for Use: The Troponin I (cTn) assay for the Opus™ Immunoassay System is a device used to measure cardiac troponin I in serum and heparinized plasma to aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991177

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 4/6/99

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K 991177
510(k) Number

Division Sign-Off
Office of Device Evaluation

Prescription Use ✓