

OCT 20 1997

K973650

DADE INTERNATIONAL

Chemistry Systems
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: 9/24/97

Device Name: Cardiac Troponin-I (TROP) Method

Classification Name: Immunoassay Method, Troponin Subunit

Predicate Device: Stratus® Cardiac Troponin-I Fluorometric Enzyme Immunoassay

Device Description: The TROP method is a one-step enzyme immunoassay. Sample is incubated with chromium dioxide particles (CrO₂) coated with a monoclonal antibody specific for cardiac troponin-I and conjugate reagent [alkaline phosphatase (ALP) labeled monoclonal antibody specific for cardiac troponin-I] to form a particle/cardiac troponin-I/conjugate sandwich. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound ALP initiates an amplification cascade. ALP dephosphorylates synthetic flavin adenine dinucleotide phosphate (FADP) to give FAD. FAD binds to APO D-amino acid oxidase and converts it to active holo D-amino acid oxidase. Each molecule of holo D-amino acid oxidase then produces multiple molecules of hydrogen peroxide (H₂O₂), which in the presence of horseradish peroxidase (HRP), converts 3,5-dichloro-2-hydroxybenzenesulfonic acid (DCHBS) and 4-aminoantipyrine (4-AAP) to a colored product that absorbs at 510nm. The color measured is directly proportional to the concentration of cardiac troponin-I present in the patient sample.

Intended Use: The TROP method is used on the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module to quantitatively

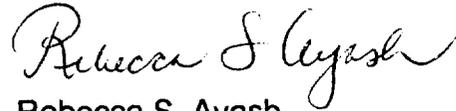
Intended Use: The TROP method is used on the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module to quantitatively measure cardiac troponin-I in human serum and plasma. Measurements of TROP aid in the diagnosis of myocardial infarction and in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.

Comparison to Predicate Device:

Item	Dimension® RxL TROP	Stratus® Cardiac Troponin-I
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Monoclonal Antibodies <ul style="list-style-type: none"> • Tag • Capture 	<ul style="list-style-type: none"> • 2B1.9 • 2F6.6 	<ul style="list-style-type: none"> • 2B1.9 • 2F6.6
Detection	Colorimetric rate measurement at 510nm and 700nm	Front surface fluorometry measurement at 577nm and 600nm
Solid Support	Chrome	Glass fiber paper
Specimen type	serum or plasma	serum or plasma
Sample Size	60µL	100µL
Intended Use	For the quantitative determination of cardiac troponin-I levels in serum and plasma	For the quantitative determination of cardiac troponin-I levels in serum and 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 TROP method on the Dimension® RxL clinical chemistry system and the Stratus® cardiac Troponin-I assay gave a correlation coefficient of 0.9918, slope of 1.10 and an intercept of -0.075 ng/mL when tested with 111 clinical patient samples ranging from 0.00 to 47.87 ng/mL.

Conclusion: The TROP method for the Dimension® RxL system with the heterogeneous immunoassay module is substantially equivalent in principle and performance to the Stratus® Cardiac Troponin-I assay based on the split sample comparison summarized on the previous page.



Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 9/24/97



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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OCT 20 1997

Re: K973650
Cardiac Troponin-I (TROP) Method
Regulatory Class: II
Product Code: MMI
Dated: September 24, 1997
Received: September 25, 1997

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 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.

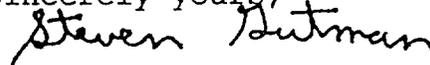
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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: Cardiac Troponin-I (TROP) Method

Indications for Use: The TROP method for the Dimension® RxL with the heterogeneous immunoassay module is a device used to measure cardiac troponin-I in serum and 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.

Rebecca S. Ayash

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 9/24/97

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

ka73650

510(k) Number

[Signature]

Division Sign-Off
Office of Device Evaluation

✓ prescription use