NOV 4 1998

K983693

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: 10/20/98

Device Name: Dimension® RxL Cardiac Troponin-I (TROP) Calibrator

Classification Name: Calibrator, secondary

Predicate Device: Dimension® RxL Cardiac Troponin-I Calibrator (K973668)

Device Description: Dimension® Cardiac Troponin-I (TROP) Calibrator is a five level frozen product with target concentrations of 0, 2, 9, 25, and 55 ng/mL containing native human troponin complex in a buffered bovine protein matrix. The kit consists of five vials; two at each level.

Intended Use: TROP Calibrator is intended to be used to calibrate the TROP Method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.

Comparison to Predicate Device:

	Dimension® RxL TROP Calibrator (Modified)	Dimension® RxL TROP Calibrator
Intended Use	Calibrator	Calibrator
Analyte	Native human troponin-I complex	Cardiac troponin-I
Matrix	Buffered bovine protein	Buffered bovine protein
Form	Frozen	Frozen
Volume	3.0 mL per vial	2.0 mL per vial
Values	Assigned	Assigned
Levels	5 levels	5 levels

Comments on Substantial Equivalence: Modified Dimension® RxL Cardiac Troponin I Calibrator is equivalent to the Dimension® RxL Cardiac Troponin-I Calibrator currently

marketed. Both products are manufactured using a buffered bovine protein matrix but differ in analyte source. Both products are intended to be used as calibrators for the Dimension® RxL Cardiac Troponin-I assay.

Conclusion: The modified Dimension® RxL Cardiac Troponin I Calibrator is substantially equivalent to the Dimension® RxL Cardiac Troponin-I Calibrator currently marketed by Dade Behring based on the comparison summarized above.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 10/20/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 4 1998

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

Re: K983693
Trade Name: Dimension® RxL Cardiac Troponin-I (TROP)
Regulatory Class: II
Product Code: JIT
Dated: October 20, 1998
Received: October 21, 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.

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: Dimension® RxL Cardiac Troponin-I (TROP) Calibrator

Indications for Use: The Cardiac Troponin-I (TROP) Calibrator is intended to be used to calibrate the Cardiac Troponin-I Method for the Dimension® RxL clinical chemistry system with the heterogeneous immunoassay module.

Rebecca S. Ayash
Regulatory Affairs and
Compliance Manager
Date: 10/20/98

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K983693
510(k) Number

Division Sign-Off
Office of Device Evaluation

✓ prescription use