

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) Calibrator

Classification Name: Calibrator, secondary

Predicate Device: Stratus® Cardiac Troponin-I Calibrators

Device Description: The Cardiac Troponin-I (TROP) Calibrator is a five level frozen product with target concentrations of 0, 2, 8, 25, and 55 ng/mL containing cardiac troponin-I in a buffered bovine protein matrix. The kit consists of five vials; two at each level.

Intended Use: The 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	Stratus® Cardiac Troponin-I Calibrators
Intended Use	Calibrator	Calibrator
Analyte	cardiac troponin-I	cardiac troponin-I
Matrix	buffered bovine protein	buffered bovine protein
Form	frozen	frozen
Volume	2.0 mL per vial	2.0 mL per vial
Values	Assigned	Nominal
Levels	5 levels	6 levels

Comments on Substantial Equivalence: Both the TROP Calibrator for the Dimension® RxL system and the Stratus® Cardiac Troponin-I Calibrators are manufactured using the same matrix and contain cardiac troponin-I as the analyte source. Both products are intended to be used as calibrators for cardiac troponin-I assays.

Conclusion: The TROP Calibrator for the Dimension® RxL system is substantially equivalent to the Stratus® Cardiac Troponin-I Calibrators based on the 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

Rebecca S. Ayash
.Regulatory Affairs and Compliance Manger
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OCT 20 1997

Re: K973668
Cardiac Troponin-I (TROP) Calibrator
Regulatory Class: II
Product Code: JIT
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.

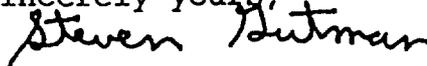
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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) Calibrator

Indications for Use: The Cardiac Troponin-I Calibrator is a device intended for medical purposes for use in a test system to establish points of reference that are used in the determination of values in the measurement of substances in human specimens.

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) _____

K 973668
510(k) Number

[Signature]
Division Sign-Off
Office of Device Evaluation

✓ prescription use
(Per 21CFR 801.19)

_____ over-the-counter use