

JUL -1 1999

K991176

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 Calibrator

Classification Name: Calibrator, secondary

Predicate Device: Dimension® RxL Troponin I Calibrator

Device Description: Opus™ Troponin I Calibrator is a six level frozen product with target concentrations of 0, 2, 8, 18, 25, 30, and 55 ng/mL containing native human troponin complex in a buffered bovine protein matrix. The kit consists of six vials packaged as one set.

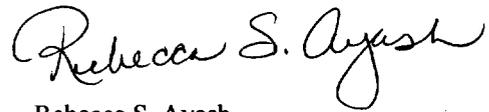
Intended Use: For calibration of the Opus™ Troponin I assay used for the quantitative measurement of cardiac troponin I in human serum and heparinized plasma.

Comparison to Predicate Device:

	Opus™ Troponin I Calibrator	Dimension® RxL Troponin I Calibrator
Intended Use	calibrator	calibrator
Analyte	native human troponin complex	native human troponin complex
Matrix	buffered bovine protein	buffered bovine protein
Form	frozen	frozen
Volume	1.0 mL per vial	3.0 mL per vial
Values	assigned	assigned
Levels	6 levels	5 levels

Comments on Substantial Equivalence: Both the Opus™ Troponin I Calibrator and the Dimension® RxL Troponin I Calibrator are manufactured using the same matrix and contain native human troponin complex as the analyte source. Both products are intended to be used as calibrators for cardiac troponin I assays.

Conclusion: The Opus™ Troponin I Calibrator is substantially equivalent to the Dimension® RxL Troponin I Calibrator based on the comparison summarized on the previous page.



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: K991176
Trade Name: Opus™ Troponin I Calibrator
Regulatory Class: II
Product Code: JIT
Dated: June 11, 1999
Received: June 15, 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.

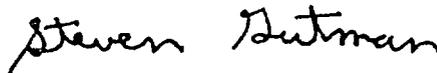
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/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

K 991176

Device Name: Opus™ Troponin I Calibrator

Indications for Use: The Opus™ Troponin I Calibrator is an *in vitro* diagnostic product intended to be used to calibrate Opus™ Troponin I Test Modules.

Dean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 991176

Rebecca S. Ayash
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 991176
510(k) Number

Division Sign-Off
Office of Device Evaluation

Prescription Use