2/16/99

K990255

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: Cathy P. Craft
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: January 22, 1999

Name of Product: Dimension® Drug Calibrator II

FDA Classification Name: Calibrator

Predicate Device: aca® Digitoxin Calibrator, K891093

Device Description: The Dimension® Drug Calibrator II is a liquid bovine serum-based product. The kit consists of ten vials; two at each of five levels.

Intended use: Drug Calibrator II is an *in vitro* diagnostic product intended for the calibration of the following methods packaged in Flex™ reagent cartridges:

Acetaminophen (ACTM)
Carbamazepine (CRBM)
Digitoxin (DGTX)
Gentamicin (GENT)
Tobramycin (TOBR)
Valproic Acid (VALP)
Vancomycin (VANC)

Comparison to Predicate Device:

Item	aca® Digitoxin Calibrator	Dimension® Drug Calibrator II
Intended Use	Calibrator	Calibrator
Analytes	digitoxin	digitoxin, acetaminophen, carbamazepine, gentamicin, tobramycin, vancomycin
Matrix	human serum base	bovine serum base
Form	lyophilized	liquid
Volume	3.0 mL per vial, reconstituted	5.0 mL per vial
Levels	3 levels	5 levels
Digitoxin Reference	Primary standard -- USP Digitoxin	Primary standard – USP Digitoxin

Comments on Substantial Equivalence: Both the aca® Digitoxin Calibrator and the Dimension® Drug Calibrator II are intended to be used as calibrators for digitoxin methods.

Conclusion: The Dimension® Drug Calibrator II is substantially equivalent to the aca® Digitoxin Calibrator based on the comparison discussed above.

Cathy P. Craft
Regulatory Affairs and Compliance Manager
Date: January 22, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 16 1999

Cathy P. Craft
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

Re: K990255
Trade Name: Dimension® Drug Calibrator II
Regulatory Class: II
Product Code: DKB
Dated: January 22, 1999
Received: January 27, 1999

Dear Ms. Craft:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

Attachment 1

510(k) Number (if known)_____

Device Name: Dimension ® Drug Calibrator II

Indications for Use:

The Dimension ®Drug Calibrator II is an *in vitro* diagnostic product intended for the calibration of the following methods packages in Flex™ reagent cartridges:

Acetominophen (ACTM)
Carbamazepine (CRBM)
Digitoxin (DGTX)
Gentamicin (GENT)
Tobramycin (TOBR)
Valproic Acid (VALP)
Vancomycin (VANC)

Dian Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990255

Cathy P. Craft
Regulatory Affairs and
Compliance Manager

February 9, 1999

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)