OCT - 6 2003

K032574

Summary of Safety and Effectiveness Information

Dade Behring Dimension® Drug Calibrator II (DC49C)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Submitter's Name:

Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: August 19, 2003

Name of Product: Dimension® Drug Calibrator II (DC49C)

FDA Classification Name: Calibrator, drug mixture (91DKB)

Predicate Device: Dimension® Drug Calibrator II (DC49B) [K990255].

Device Description:

The predicate Drug Calibrator II product labeling is being modified to include the assigned values for the additional N-acetylprocainamide (NAPA) and procainamide (PROC) constituents.

The Dimension® Drug Calibrator II is a liquid, bovine serum base product. It is packaged as ten vials, two vials at each of five levels. Each vial contains 5.0 mL.

Intended Use:

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

Acetaminophen (ACTM)
Carbamazepine (CRBM)
Digitoxin (DGTX)
Gentamicin (GENT)
N-acetylprocainamide (NAPA)
Procainamide (PROC)
Tobramycin (TOBR)
Valproic acid (VALP)
Vancomycin (VANC)

Comparison to Predicate Device:

A summary of the features of the proposed Dade Behring Dimension® Drug Calibrator II (DC49C) product and the predicate Dimension® Drug Calibrator II product (DC49B) [K990255] is provided in the following chart:

	Proposed Dade Behring Drug Calibrator II (DC49C)	***Current*** Dade Behring Drug Calibrator II (DC49B)
Intended Use:	For calibration of the following nine (9) Dimension® Flex® methods: Acetaminophen (ACTM) Carbamazepine (CRBM) Digitoxin (DGTX) Gentamicin (GENT) N-acetylprocainamide (NAPA) Procainamide (PROC) Tobramycin (TOBR) Valproic acid (VALP) Vancomycin (VANC)	For calibration of the following seven (7) Dimension® Flex® methods: Acetaminophen (ACTM) Carbamazepine (CRBM) Digitoxin (DGTX) Gentamicin (GENT) ---------- ---------- ---------- ---------- Tobramycin (TOBR) Valproic acid (VALP) Vancomycin (VANC)
Matrix:	Bovine serum base	Bovine serum base
Form:	Liquid	Liquid
Package:	Ten vials -five levels, two vials/level, 5.0 mL/vial	Ten vials - five levels, two vials/level, 5.0 mL/vial
Value Assignment:	USP standards or highest-order purity material available	USP standards or highest-order purity material available

Comments on Substantial Equivalence:

Both the proposed Dade Behring Dimension® Drug Calibrator II (DC49B) and the existing Dade Behring Dimension® Drug Calibrator II (DC49B) [K990255] are *in vitro* diagnostic products intended as calibrators for the specified Dimension® Flex® methods on Dade Behring Dimension® clinical chemistry analyzer systems.

The only difference in the product offerings is that the proposed Dimension® Drug Calibrator II (DC49C) has value assignments for the calibration of the additional Dade Behring Dimension® N-acetylprocainamide (NAPA) and Procainamide (PROC) Flex® reagent cartridge methods.

Conclusion:

Based on the same design, manufacture and intended use as described above, the multi-analyte, five level, bovine serum base Dimension® Drug Calibrator II products (DC49C and DC49B) are substantially equivalent. The only difference is the assigned values for the two additional analytes (procainamide and n-acetylprocainamide).

Richard M. Vaught
Regulatory Affairs and Compliance Manager
August 19, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT - 6 2003

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, DE 19714

Re: k032574
Trade/Device Name: Dimension® Drug Calibrator II (DC49C)
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DKB
Dated: August 19, 2003
Received: August 20, 2003

Dear Mr. Vaught:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: Dimension® Drug Calibrator II (DC49C)

Indications for Use:

The Dade Behring Dimension® Drug Calibrator II is a device intended for medical purposes for use on the Dade Behring Dimension® clinical chemistry system to establish points of reference that are used in determination of values in the measurement of substances in human specimens. The product is intended for the calibration of the following methods packaged in Dimension® Flex® reagent cartridges:

Acetaminophen (ACTM)
Carbamazepine (CRBM)
Digitoxin (DGTX)
Gentamicin (GENT)
N-acetylprocainamide (NAPA)
Procainamide (PROC)
Tobramycin (TOBR)
Valproic acid (VALP)
Vancomycin (VANC)

Richard M. Vaught
Regulatory Affairs and Compliance Manager

August 19, 2003

(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)

(Optional format 1-2-96)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032574