K033809

FEB 2 0 2004

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:

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P.O. Box 6101
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Date of Preparation: December 5, 2003

Name of Product(s): Dimension® Lidocaine (LIDO) Flex® reagent cartridge method and Dimension® Drug Calibrator II (DC49D)

FDA Classification Name(s): Lidocaine test system (Class II) and Calibrator (Class II)

Predicate Device(s): Dade Behring aca® LIDO analytical test pack [K833379] and Dade Behring Dimension® Drug Calibrator II (DC49C) [K032574]

Device Description(s):

Method

The Dade Behring Dimension® Lidocaine (LIDO) Flex® reagent cartridge method is an *in vitro* diagnostic test that consists of prepackaged reagents in a flexible plastic cartridge for use only on the Dimension® clinical chemistry system. The Dimension® LIDO Flex® reagent cartridge assay is based on a homogenous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) which uses a latex particle-lidocaine conjugate and monoclonal lidocaine specific antibody. Lidocaine present in the sample competes with lidocaine on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of lidocaine in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm.

Calibrator

The Dade Behring Drug Calibrator II (DC49D) is liquid, bovine serum base product, packaged as ten vials to a carton, with two vials at each of five levels; each vial contains 5.0 mL. This same product, the Dade Behring Drug Calibrator II (DC49C), was previously cleared (K032574) for calibration of its associated methods on the Dimension® clinical chemistry system. The product remains unchanged except for the additional value assignment for the Lidocaine constituent. The DC49D product contains the following value assigned analytes and one unassigned constituent (Quinidine):

1 -Lidocaine (LIDO)
2- Acetaminophen (ACTM)
3- Carbamazepine (CRBM)
4- Digitoxin (DGTX)
5- Gentamicin (GENT)
6- N-acetylprocainamide (NAPA)
7- Procainamide (PROC)
8- Tobramycin (TOBR)
9- Valproic acid (VALP)
10- Vancomycin (VANC)

Unassigned: Quinidine

Intended Use:

Method

The Dimension® Lidocaine (LIDO) Flex® reagent cartridge method is used for the quantitative determination of lidocaine in serum or plasma. Measurements may be used in the diagnosis and treatment of lidocaine overdose, and in therapeutic drug monitoring.

Calibrator

The Dimension® Drug Calibrator II (DC49D) is intended for calibration of the above ten (10) value-assigned methods on the Dade Behring Dimension® clinical chemistry system.

Comparison to Predicate Device(s):

Method

A summary of the features of the Dade Behring Dimension® LIDO Flex® reagent cartridge method and the predicate device, the Dade Behring aca® LIDO analytical test pack (K833379) is provided in the following chart:

Feature	Dimension® LIDO Flex® cartridge	aca® LIDO analytical test pack
Intended Use	*in vitro* diagnostice use	*in vitro* diagnostic use
Assay Range	0.5 – 12.0 ug/mL	1.0 – 12.0 ug/mL
Sample size	6 uL	40 uL
Measurement	PETINIA turbidimetric rate 340 nm and 700nm	EMIT® [1] colorimetric rate 340 nm

[1] Registered trademark of Syva Company, Dade Behring Inc.

Split-sample comparative performance was evaluated between the Dade Behring Dimension® LIDO Flex® method and the predicate aca® LIDO analytical test pack method. The results are summarized below:

Comparative Method	Slope	Intercept (ug/mL)	Correlation Coefficient	n
Dade Behring aca® LIDO test pack	0.985	- 0.037	0.99	120

Calibrator

The Dimension Drug Calibrator II (DC49D) is identical in design and content to the currently cleared Drug Calibrator II (DC49C) product with the exception of the labeling change to identify the Lidocaine values at each level. There are no other differences in the design or manufacture of the Drug Calibrator II product.

Comments on Substantial Equivalence:

Both Dade Behring products, the Dimension® Lidocaine (LIDO) Flex® reagent cartridge method and the aca® LIDO analytical test pack method are homogenous immunoassays intended for the quantitative determination of lidocaine in serum or plasma. Split-sample comparative data demonstrates good agreement (correlation) between the methods. The calibrator products are identical except the value assignments to the lidocaine constituent.

Conclusion:

The Dade Behring Dimension® Lidocaine (LIDO) Flex® reagent cartridge method and the predicate Dade Behring aca® LIDO analytical test pack method (K833379) are substantially equivalent based on their intended use and comparison performance characteristics as described above. The Dade Behring Dimension® Drug Calibrator II products (DC49C and DC49D) are identical in composition and design and are both utilized for calibration of methods on the Dimension® system.

Richard M. Vaught
Regulatory Affairs and Compliance Manager
December 5, 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 0 2004

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
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Glasgow Business Community
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Re: k033809
Trade/Device Name: Dimension® Lidocaine (LIDO) Flex® reagent cartridge method, and Dimension® Drug Calibrator II (DC49D)
Regulation Number: 21 CFR 862.3555
Regulation Name: Lidocaine test system
Regulatory Class: Class II
Product Code: KLR; DKB
Dated: December 5, 2003
Received: December 8, 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device(s) Name(s):

Dimension® Lidocaine (LIDO) Flex® reagent cartridge method, and
Dimension® Drug Calibrator II (DC49D)

Indications for Use:

The Dade Behring Dimension® Lidocaine (LIDO) Flex® reagent cartridge method on the Dimension® clinical chemistry system is for the quantitative determination of lidocaine in serum or plasma. Lidocaine measurements may be used in the diagnosis and treatment of lidocaine overdose and in therapeutic drug monitoring.

The Dade Behring Dimension® Drug Calibrator II (DC49D) is a device intended for medical purposes for use on the Dimension® clinical chemistry system to establish points of reference that are used in determination of values in the measurement of substances in human specimens.

Richard M. Vaught
Regulatory Affairs and Compliance Manager

February 2, 2004

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C. Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033809

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)