K032573

OCT 3 1 2003

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

Date of Preparation: August 19, 2003

Name of Product: Dimension® Procainamide (PROC) Flex® reagent cartridge method

FDA Classification Name: Procainamide test system (21CFR§862.3320; 91LAR)

Predicate Device: Dade Behring aca® PROC analytical test pack (K833384)

Device Description:
The Dade Behring Dimension® Procainamide (PROC) 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® PROC Flex® reagent cartridge assay is based on a homogenous particle-enhanced turbidimetric inhibition immunoassay (PETINIA) which uses a latex particle procainamide conjugate and monoclonal procainamide specific antibody. Procainamide present in the sample competes with procainamide on the particles for available antibody, thereby decreasing the rate of aggregation. Hence, the rate of aggregation is inversely proportional to the concentration of procainamide in the sample. The rate of aggregation is measured using bichromatic turbidimetric readings at 340 nm and 700 nm.

Intended Use:
The Dimension® Procainamide (PROC) Flex® reagent cartridge method is used for the quantitative determination of procainamide in serum or plasma. Measurements may be used in the diagnosis and treatment of procainamide overdose, and in therapeutic drug monitoring.

Comparison to Predicate Device:
A summary of the features of the Dade Behring Dimension® PROC Flex® reagent cartridge method and the predicate device, the Dade Behring aca® PROC analytical test pack (K833384) is provided in the following chart:

	Dimension® PROC Flex® cartridge	aca® PROC analytical test pack
Intended Use	*in vitro* diagnostice use	*in vitro* diagnostic use
Assay Range	0.5 – 20.0 ug/mL	1.0 – 16.0 ug/mL
Sample size	2 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® PROC Flex® method and the predicate aca® PROC analytical test pack method. The results are summarized below:

Comparative Method	Slope	Intercept (ug/mL)	Correlation Coefficient	n
Dade Behring aca® PROC test pack	1.03	-0.02	0.997	89

Comments on Substantial Equivalence:
Both Dade Behring products, the Dimension® Procainamide (PROC) Flex® reagent cartridge method and the aca® PROC analytical test pack method are homogenous immunoassays intended for the quantitative determination of procainamide in serum or plasma. Split-sample comparative data demonstrates good agreement (correlation) between the methods.

Conclusion:
The Dade Behring Dimension® Procainamide (PROC) Flex® reagent cartridge method and the predicate Dade Behring aca® PROC analytical test pack method (K833384) are substantially equivalent based on their intended use, design and comparison performance characteristics as described above.

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 3 1 2003

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

Re: k032573
Trade/Device Name: Dimension® Procainamide (PROC) Flex® reagent cartridge method
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: LAR
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® Procainamide (PROC) Flex® reagent cartridge method

Indications for Use:

The Dade Behring Dimension® Procainamide (PROC) Flex® reagent cartridge method is used to measure procainamide in serum or plasma. Measurements obtained may be used in the diagnosis and treatment of procainamide overdose and in monitoring levels of procainamide to ensure appropriate therapy.

RM Vaught

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)

for Ian Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032573