FEB - 9 2004

510(k) Summary for the
Expansion of the Indications for Use to include a 150 ng/mL cutoff for the Dimension®Urine Cocaine Metabolite Screen (COC) Flex® reagent cartridge

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.

510(k) Number: K033713

Analyte: cocaine metabolite

Type of Test: qualitative or quantitative homogeneous enzyme immunoassay

A. Applicant: Dade Behring Inc.

1. Submitter's Name
Andrea M. Tasker
Building 500, Mailbox 514
P.O.Box 6101
Newark, DE 19714-6101

2. Submission Preparation Date
November 25, 2003

B. Proprietary and Established Names: Dimension® Urine Cocaine Metabolite Screen Flex® reagent

C. Regulatory Information:

1. Regulation section: 21CFR862.3250, Cocaine and Cocaine Metabolite test system

2. Classification: Class II

3. Product Code: 91 DIO

4. Panel: Toxicology (91)

D. Intended Use:

1. Indications for Use: The COC Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine using a cutoff of 150 or 300 ng/mL. Measurements obtained with the COC method are used in the diagnosis and treatment of cocaine use or overdose.

2. Special conditions for use statements: **The COC method provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.**

E. Device Description:

The Dade Behring Dimension® COC method is an *in vitro* diagnostic device that consists of prepackaged reagents in a plastic cartridge (Flex®) for use on the Dade Behring Dimension® clinical chemistry system.

F. Substantial Equivalence Inforamtion:

1. Predicate Device: Syva® Emit® II Plus polyclonal Cocaine Metabolite Assay

2. Predicate K Number(s): K031512

3. Comparision with Predicate: Indications for use, sample type, cutoff concentration, technology and composition of reagents are similar to the predicate device. The change to the device to expand the indications for use to include a 150ng/mL cutoff includes performance claims for the correct identification of near-cutoff samples.

H. Device Performance Characteristics:

1. Method Comparison (Semi-Quantitative Results)

COC Flex® reagent cartridge on the Dimension® clinical chemistry system (Cutoff 150ng/mL)		Emit® II Plus polyclonal Cocaine Metabolite Assay on the SYVA®-30R (Cutoff 150ng/mL)	
		+	−
	+	69	2
	−	2	52

Discrepant specimens (ng/mL): All discrepants were within +/- 25% of the cutoff.

Dimension® system	Syva 30R®	GC/MS (benzoylecgonine)
142	150	151
147	164	164
159	135	123
150	144	156

COC Flex® reagent cartridge on the Dimension® clinical chemistry system (Cutoff 150ng/mL)		GC/MS (cutoff 150 ng/mL)	
		+	−
	+	66	5
	−	3	51

Discrepant specimens (ng/mL): All discrepants were within +/- 25% of the cutoff.

Dimension® System	GC/MS (benzoylecgonine)
160	123
183	123
168	134
151	140
169	140
143	151
143	157
147	164

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Andrea M. Tasker
Senior Specialist
Regulatory Affairs and Compliance
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Re: k033713
Trade/Device Name: Dimension® Urine Cocaine Metabolite Screen (COC) Flex® reagent cartridge
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: November 25, 2003
Received: November 26, 2003

Dear Ms. Tasker:

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, D.V.M.

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 Name:

Dimension® Urine Cocaine Metabolite Screen (COC) Flex® reagent cartridge

Indications for Use:

The COC Flex® reagent cartridge used on the Dimension® clinical chemistry system provides reagents for an *in vitro* diagnostic test intended for the qualitative and semi-quantitative determination of benzoylecgonine (cocaine metabolite) in human urine using a cutoff of 150 or 300 ng/mL. Measurements obtained with the COC method are used in the diagnosis and treatment of cocaine use or overdose.

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See hard copy for signature page.

Andrea M. Tasker
Senior Regulatory Affairs and Compliance Specialist
November 25, 2003

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use__X__ OR Over-the-counter Use_____
(Per 21 CFR 801.109) (Optional format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K033713