APR - 8 2004

510(k) Summary for the
Dimension® Urine Amphetamines/Methamethamine Screen Flex® (DF91B)

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: K040133

Analyte: Amphetamines/Methamethamine

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
January 20, 2004

B. Proprietary and Established Names: Dimension® Urine Amphetamines/Methamethamine Screen Flex® reagent cartridge

C. Regulatory Information:

1. Regulation section: 21CFR §862.3100 Amphetamine test system

2. Classification: Class II

3. Product Code: DKZ

4. Panel: Toxicology (91)

D. Intended Use:

1. Indications for Use: The AMPH 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 amphetamines in human urine using a cutoff of either 300, 500 or 1000ng/mL. Measurements obtained with the AMPH method are used in the diagnosis and treatment of amphetamines use or overdose.

2. Special conditions for use statements: **The AMPH 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® AMPH 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 Amphetamine Assay
2. Predicate K Number(s): K031004
3. Comparision with Predicate: This product is substantially equivalent to other Amphetamine enzyme immunoassys, such as the Syva® Emit® II Plus Amphetamine Assay (K031004).

I. Device Performance Characteristics:
Method Comparison (cutoff=300 ng/mL)

129 native urine specimens were tested with the AMPH Flex® cartridge on the Dimension® system (cutoff=300 ng/mL) and with the Syva® Emit® II Plus Amphetamines Assay (9C309UL) on the Syva 30R® Biochemical System (cutoff=300 ng/mL). All 129 specimens were also analyzed by GC/MS. Positives by GC/MS were determined by using the criteria of amphetamine plus methamphetamine ≥ 300 ng/mL since there are no SAMSHA confirmation guidelines for the 300 cutoff. 24 of these had total amphetamines by GC/MS within 25% of the 300 ng/mL cutoff.

Comparison to Predicate Method

		Syva 30R® Biochemical System (cutoff 300 ng/mL)	
		+	−
AMPH Flex® Reagent Cartridge on the Dimension® clinical chemistry system (cutoff 300 ng/mL)	+	70	2
	−	2	55

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	GC/MS Total	Dim AMPH	Syva 30R
242	61.1	303	315	273
433	< lod	433	325	298
275	70.2	345	278	300
363	< lod	363	204	301

< lod : less than the limit of detection, < 25 ng/mL

Comparison to Reference Method

AMPH Flex® Reagent Cartridge on Dimension® clinical chemistry system (cutoff 300 ng/mL)		GC/MS (cutoff 300 ng/mL methamphetamine and amphetamine)	
		+	–
	+	72	0
	–	8	49

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	GC/MS Total	Dim AMPH
253	47.2	300	95
311	< lod	311	240
326	< lod	326	189
313	< lod	313	240
363	< lod	363	204
255	67.3	322	271
275	70.2	345	278
279	71	350	296

< lod: less than the limit of detection of 25 ng/mL

Method Comparison (cutoff=500 ng/mL)

129 native urine specimens were tested with the AMPH Flex® cartridge on the Dimension® system (cutoff=500 ng/mL) and with the Syva® Emit® II Plus Amphetamines Assay (9C309UL) on the Syva 30R® Biochemical System (cutoff=500 ng/mL). All 129 specimens were also analyzed by GC/MS. Positives by GC/MS were determined using the newly proposed SAMHSA guidelines by following the criteria of ≥ 250 ng/mL methamphetamine and ≥ 100 ng/mL amphetamine or ≥ 250 ng/mL amphetamine regardless of the methamphetamine concentration. 28 of these had total amphetamines by GC/MS within 25% of the 500 ng/mL cutoff.

Comparison to Predicate Method

		Syva 30R® Biochemical System (cutoff 500 ng/mL)	
		+	−
AMPH Flex® Reagent Cartridge on the Dimension® clinical chemistry system (cutoff 500 ng/mL)	+	43	0
	−	1	85

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	Dim AMPH	Syva 30R
556	62.7	405	598

Comparison to Reference Method

AMPH Flex® Reagent Cartridge on Dimension® clinical chemistry system (cutoff 500 ng/mL)		GC/MS (cutoff ≥ 250 ng/mL amphetamine or ≥ 250 ng/mL metamphetamine and ≥ 100 ng/mL amphetamine)	
		+	–
	+	34	9
	–	5	81

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	Dim AMPH
410	36.7	550
506	43.6	572
513	44.8	564
528	47.9	572
561	48.6	507
577	50.5	574
514	56.1	534
495	58.4	548
598	64.5	561
286	169	366
281	173	388
254	174	344
300	179	398
315	186	393

Method Comparison (cutoff=1000 ng/mL)

169 native urine specimens were tested with the AMPH Flex® cartridge on the Dimension® system (cutoff=1000 ng/mL) and with the Syva® Emit® II Plus Amphetamines Assay (9C309UL) on the Syva 30R® Biochemical System (cutoff=500 ng/mL). Total amphetamine and methamphetamine values by GC/MS were reported for these 169 specimens. Positives by Confirmation GC/MS were determined according to the SAMHSA requirements by following the criteria of ≥ 500 ng/mL methamphetamine and ≥ 200 ng/mL amphetamine or ≥ 500 ng/mL amphetamine regardless of the methamphetamine concentration.

Separate amphetamine and methamphetamine values were available for only 129 of thes 169 specimens. Since separate amphetamine and methamphetamine values are required for confirmation testing according to the SAMSHA guidelines, only those 129 samples were represented in the box plot shown in Table 10. Of these 129, there were 9 which had total amphetamines by GC/MS within 25% of the 1000 ng/mL cutoff.

Comparison to Predicate Method

		Syva 30R® Biochemical System (cutoff 1000 ng/mL)	
		+	–
AMPH Flex® Reagent Cartridge on the Dimension® clinical chemistry system (cutoff 1000 ng/mL)	+	62	0
	–	2	105

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	Dim AMPH	Syva 30R
713	534	929	1134
494	844	922	aar

aar: above assay range, > 2000 ng/mL

Comparison to Reference Method

AMPH Flex® Reagent Cartridge on Dimension® clinical chemistry system (cutoff 1000 ng/mL)		GC/MS (cutoff ≥ 500 ng/mL amphetamine or ≥ 500 ng/mL metamphetamine and ≥ 200 ng/mL amphetamine)	
		+	–
	+	16	6
	–	8	99

Discrepants (ng/mL):

GC/MS Meth	GC/MS Amph	Dim AMPH
1223	118	1264
1209	127	1347
1112	172	1395
1183	174	1314
1213	177	1414
1194	180	1367
631	202	627
652	214	375
713	534	929
496	615	682
390	624	681
333	635	648
494	844	922
161	1032	770

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR - 8 2004

Ms. Andrea M. Tasker
Senior Regulatory Affairs and Compliance Manger
Dade Behring, Inc
Chemistry/ Immunochemistry
Glasgow Business Community;
BLDG. 500 PO Box 6101
Newark, DE 19714

Re: k040133
Trade/Device Name: Dimension® Urine Amphetamine/ Methamphetamine Screen Flex® reagent cartridge (DF91B)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ
Dated: January 20, 2004
Received: January 21, 2004

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, 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 Name: K040133

Dimension® Urine Amphetamine/Methamphetamine Screen Flex® reagent cartridge (DF91B)

Indications for Use:

The AMPH 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 amphetamines in human urine using a cutoff of either 300, 500 or 1000ng/mL. Measurements obtained with the AMPH method are used in the diagnosis and treatment of amphetamines use or overdose.

The AMPH 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.

Andrea M. Tasker
Regulatory Affairs and Compliance Manager

January 20, 2004

(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 Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040133