510(k) Summary
EXTC Flex® reagent cartridge

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

The assigned 510(k) number is: K053337

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	Nov. 29, 2005

2. Device Name / Classification

Dimension® Urine Ecstasy Screen Flex® reagent cartridge / Amphetamine Test System
Classification: Class II (862.3100)

3. Identification of the Predicate Device

Emit® II Plus Ecstasy Assay, K043028

4. Device Description

The Dimension® Urine Ecstasy Screen Flex® reagent cartridge is an in vitro diagnostic device that consists of prepackaged reagents in a plastic eight-well cartridge for use on the Dade Behring Dimension® clinical chemistry system.

5. Device Intended Use

The EXTC 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 methylenedioxymethamphetamine (MDMA) and closely related drugs in human urine using a cutoff of either 300 or 500 ng/mL. Measurements obtained with the EXTC method are used in the diagnosis and treatment of ecstasy use or overdose.

The EXTC 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.

6. Medical device to which equivalence is claimed and comparison information

The EXTC Flex® reagent cartridge is substantially equivalent in intended use and methodology to the Emit® II Plus Ecstasy Assay (K043028). Both devices are enzyme immunoassays intended for use in the qualitative and semiquantitative determination of ecstasy drugs in human urine. Both assays have two cutoffs: 300 ng/mL and 500 ng/mL.

Method comparison studies were conducted with the EXTC Flex® reagent cartridge on the Dimension® clinical chemistry system vs. a reference method (GC/MS). Results are summarized in the 2 x 2 concordance tables below.

Comparison to GC/MS at the 300 ng/mL cutoff

		Reference Method GC/MS	
		Positive	Negative
EXTC Flex® reagent cartridge on the Dimension® clinical chemistry system	Positive	73	0
	Negative	11	54

% agreement = 92%

Comparison to GC/MS at the 500 ng/mL cutoff

		Reference Method GC/MS	
		Positive	Negative
EXTC Flex® reagent cartridge on the Dimension® clinical chemistry system	Positive	58	0
	Negative	11	56

% agreement = 91.2%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Yuk-Ting Lewis
Regulatory Affairs & Compliance Manager
Dade Behring Inc.
PO Box 6101, M/S 514
Newark DE, 19714

MAY 19 2006

Re: k053337
Trade/Device Name: Dimension® Urine Ecstasy Screen Flex® reagent cartridge
Regulation Number: 21 CFR§862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: May 8, 2006
Received: May 9, 2006

Dear Ms. Lewis:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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

510(k) Number (if known): K053337

Device Name: **Dimension® Urine Ecstasy Screen Flex® reagent cartridge**

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Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional) K053337