MAR 2 8 2002

510(k) Summary for
Emit® II Plus Monoclonal Cocaine Metabolite Assay

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.

The assigned 510(k) number is: K020441

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

Manufacturer:	Syva Company – Dade Behring Inc. 20400 Mariani Ave Cupertino, CA 95014
Contact Information:	Dade Behring Inc. Glasgow Site P.O. Box 6101 Newark, Delaware 19714 Attn: Kathleen Dray-Lyons Tel: 781-826-4551 Fax: 781-826-2497
Preparation date:	March 26, 2002

2. Device Name/ Classification:

Emit® II Plus Monoclonal Cocaine Metabolite Assay:	Cocaine and cocaine metabolite test system Class II (862.3250)
Product Code:	91 DIO

3. Identification of the Legally Marketed Device:

Emit® II Plus Cocaine Metabolite Assay (K011162)

4. Device Description:

Emit® II Plus Monoclonal Cocaine Metabolite Assay is a homogeneous enzyme immunoassay for qualitative and semi-quantitative analysis of cocaine metabolite (benzoylecgonine) in human urine.

5. Device Intended Use:

The Emit® II Plus Monoclonal Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff (SAMSHA initial test cutoff level). The assay is intended for use in the qualitative and semi-quantitative analyses of benzoylecgonine (cocaine metabolite) in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Monoclonal Cocaine Metabolite Assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used 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 modified Emit® II Plus Monoclonal Cocaine Metabolite Assay is substantially equivalent in intended use to the Emit® II Plus Cocaine Metabolite Assay currently marketed. The modified Emit® II Plus Monoclonal Cocaine Metabolite Assay, like the current Emit® II Cocaine Metabolite Assay is intended to be used for the qualitative and semi-quantitative analyses of cocaine metabolite (benzoylecgonine) in human urine.

7. Device Performance Characteristics:

Method Comparison:

Qualitative Results

150 ng/mL CUTOFF
One hundred and ten (110) samples were analyzed by the Emit® II Plus Monoclonal Cocaine Metabolite Assay and the Emit® II Plus Cocaine Metabolite Assay on the SYVA®-30R Biochemical System. Forty-six (46) samples showed positive results by both methods, and 60 samples showed negative results by both methods. Of the forty-six (46) specimens showing positive results by the Emit® II Plus Monoclonal Cocaine Metabolite Assay, forty-two (42) were confirmed by GC/MS to contain cocaine metabolite between 150 ng/mL and greater than 1000 ng/mL benzoylecgonine. Data are summarized in the table below.

Qualitative Results for the 150 ng/mL Cutoff

		Comparative Method	
		+	-
Emit® II Plus Monoclonal Cocaine Metabolite Assay	+	46	0
	-	4 *	60

*** Shown to contain 25, 46, 99 and 110 ng/mL benzoylecgonine as determined by GC/MS.**

Of the one hundred (110) method comparison samples, 19% were within ±25% of the cutoff value.
Percent Agreement: 96%

300 ng/mL CUTOFF

One hundred and ten (110) samples were analyzed by the Emit® II Plus Monoclonal Cocaine Metabolite Assay and the Emit® II Plus Cocaine Metabolite Assay on the SYVA®-30R Biochemical System. Twenty-nine (29) samples showed positive results by both methods, and seventy-nine (79) samples showed negative results by both methods. Of the twenty-nine (29) samples showing positive results by the Emit® II Plus Monoclonal Cocaine Metabolite Assay, twenty-eight (28) were confirmed by GC/MS to contain cocaine metabolite between 300 ng/mL and greater than 1000 ng/mL benzoylecgonine. Data are summarized in the table below.

Qualitative Results for the 300 ng/mL Cutoff

		Comparative Method	
		+	-
Emit® II Plus Monoclonal Cocaine Metabolite Assay	+	29	0
	-	2 *	79

**** Shown to contain 218 and, 235 ng/mL benzoylecgonine as determined by GC/MS.***

Of the one hundred (110) method comparison samples, 16% were within ±25% of the cutoff value.
Percent Agreement: 98%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 8 2002

Ms. Kathleen A. Dray-Lyons
Manager, Regulatory Affairs and Compliance
Dade Behring Inc.
Glasgow Site
P.O. Box 6101
Newark, DE 19714

Re: k020441
Trade/Device Name: Emit ® II Plus Monoclonal Cocaine Metabolite Assay
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: February 8, 2002
Received: February 11, 2002

Dear Ms. Dray-Lyons:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Name: Emit® II Plus Monoclonal Cocaine Metabolite Assay

Indications for Use:

The Emit® II Plus Monoclonal Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff (SAMSHA initial test cutoff level). The assay is intended for use in the qualitative and semi-quantitative analyses of benzoylecgonine (cocaine metabolite) in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020441

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Over-The-Counter-Use _____
(Optional Format 1-2-96)