

JAN 27 2000

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS****1. Manufacturer and Contact Information:**

Manufacturer: Syva Company- Dade Behring Inc.  
20400 Mariani Ave.  
Cupertino, CA 95014

Contact Information: Paul Rogers  
Syva Company- Dade Behring Inc,  
3403 Yerba Buena Road  
San Jose, CA 95161-9013  
Tel: 408-239-2309

**2. Device Classification Name:**

"Cocaine metabolite test system" has been classified as Class II Reference: 21  
CRF§862.3250, revised April 1, 1998

**3. Intended Use:**

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of benzoylecognine (cocaine metabolite) in human urine. The Emit® II Plus 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 judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

**4. Device Description and Characteristics:**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous enzyme immunoassay with a 150 ng/mL or 300 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of benzoylecognine (cocaine metabolite) in human urine. The Emit® II Plus Cocaine Metabolite Assay and has been found to be equivalent to the predicate device: Emit® II Cocaine Metabolite Assay with regard to intended use, assay sample, and overall performance characteristics.

### **Comparative Analysis:**

The Emit® II Plus Cocaine Metabolite Assay showed excellent correlation to GC/MS (reference method) for the optional 150 ng/mL cutoff level. The GC/MS reference method has a limit of quantitation (LOQ) of 30 ng/mL. The percent agreement between these methods was 100%. The Emit® II Plus Cocaine Metabolite Assay showed excellent correlation between Emit® II Cocaine Metabolite Assay and The Emit® II Cocaine Metabolite Assay (comparative method) at the 300 ng/mL cutoff level. The percent agreement between these methods was 98%. Three samples were discordant and were analyzed by GC/MS. These samples were borderline positive with the Emit® II Plus 300 ng/mL Cocaine Metabolite Assay. These borderline results were with-in the precision limit of the Emit® II Cocaine Metabolite Assay (comparative method).

All positive samples and a portion of negative samples (n=20), as assessed by the Emit® II Plus Cocaine Assay, were analyzed by GC/MS for confirmatory (positive samples) and specificity (negative samples) purposes.

### **Spiked Sample Recovery:**

The qualitative and semiquantitative attributes were assessed by determining the accuracy for the analyte in spiked samples by the Emit® II Plus Cocaine Metabolite Assay.

#### **Qualitative -150 ng/mL cutoff**

Known levels of benzoylecognine, spiked at levels less than or equal to the minus 25% of the 150 ng/mL cutoff (0-112.5 ng/mL) were distinguished as negative. Spiked levels greater than or equal to plus 25% for the 150 ng/mL cutoff (187 – 3000 ng/mL) were routinely distinguished positive.

#### **Qualitative – 300 ng/mL cutoff**

Known levels of benzoylecognine, spiked at levels less than or equal to minus 25% of the 300 ng/mL cutoff (0-225 ng/mL) were distinguished as negative. Spiked levels greater than or equal to plus 25% of the 300 ng/mL cutoff (375– 3000 ng/mL) were routinely distinguished positive.

The semiquantitative results for known spiked concentrations for the Emit® II Plus 150/300 ng/mL Cocaine Metabolite assay recovered with-in 20% of the nominal value between 45 ng/mL and 900 ng/mL.

### **Precision:**

A precision study was performed on the two cutoff levels (150/300ng/mL) using the Emit® II Plus Cocaine Metabolite Assay in both the qualitative and semiquantitative modes. Acceptable with-in run and total precision statistics in both the qualitative and the semiquantitative assays were observed.

In the qualitative mode the with-in run precision demonstrated coefficients of variation (%CV) for controls and cutoffs (rates) ranged from 0.4 to 0.5% and the total precision with %CV's for controls and cutoff (rates) ranged from 0.5 to 0.6%.

In the semiquantitative mode the with-in run precision demonstrated coefficient of variation (%CV) for controls and cutoffs (concentrations) ranged from 3.7 to 10.9 % and the total precision %CV's for controls and cutoff (concentrations) ranged from 5.1 to 14.9%.

**5. Substantial Equivalence:**

In conclusion, SYVA Company- Dade Behring Inc. considers the Emit® II Plus Cocaine Metabolite Assay to be substantially equivalent to the Emit® II Cocaine Metabolite Assay with regard to intended use, assay sample, and overall performance characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JAN 27 2000

Mr. Paul L. Rogers, Jr.  
Senior Manager, Regulatory Affairs  
Syva Company – Dade Behring Inc.  
3403 Yerba Buena Road  
P.O. Box 49013  
San Jose, California 95161-9013

Re: K993988  
Trade Name: Emit® II Plus Cocaine Metabolite Assay  
Regulatory Class: II  
Product Code: DIO  
Dated: November 24, 1999  
Received: November 24, 1999

Dear Mr. Rogers:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895.

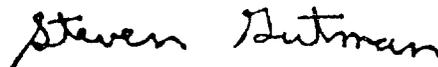
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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

K 993988

Device Name: Emit® II Plus Cocaine Metabolite Assay

**Indications for Use:**

The Emit® II Plus Cocaine Metabolite Assay is a homogeneous drugs-of-abuse 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 semiquantitative 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 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 judgement should be applied to any drug-of-abuse test result, particularly when preliminary positive results are used.

Dean Cozler  
(Division Sign-Off) \_\_\_\_\_  
Division of Clinical Laboratory Devices  
510(k) Number K 993988

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

over-the-counter Use \_\_\_\_\_

(Optional Format 1-2-96)

Device Name: Emit® II Plus Cocaine Metabolite Assay