JAN 2 7 2000

k993983

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:**
"Phencyclidine test system" has been classified as Class II by the Clinical Chemistry and Clinical Toxicology Devices Panel. Reference: Federal Register, Volume 52, Number 84, May 1987

3. **Intended Use:**
The Emit® II Plus Phencyclidine Assay is a homogeneous enzyme immunoassay with a 25 ng/mL cutoff (SAMHSA initial test cutoff level). The assay is intended for use in the qualitative and semiquantitative analyses of phencyclidine in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Phencyclidine 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.

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 Phencyclidine Assay is a homogenous enzyme assay intended for use in qualititative and semiquantitative analysis of phencyclidine in human urine. The Emit® II Plus Phencyclidine Assay and has been found to be equivalent to the predicate device: Emit® II Phencyclidine Assay with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis

The Emit® II Plus Phencyclidine Assay showed excellent correlation to the Emit ® II Phencyclidine Assay (comparative method) for the qualitative analysis. One hundred specimens were tested. Forty nine (49) samples were positive and Fifty samples were negative by both methods. The percent agreement between the Emit ® II Plus Phencyclidine Assay and the comparative method using the 25 ng/mL cutoff result was 99%. One (1) discordant sample was positive by the Emit® II Plus Phencyclidine 25 Assay and negative by the Emit® II Phencyclidine assay was shown to have 15 ng/mL of PCP by GC/MS. The GC/MS (reference method) has a limit of quantitation (LOQ) of 2.0 ng/mL.

All positive samples and a portion of negative samples (n=20), as assessed by the Emit® II Plus assay, were analyzed by GC/MS for confirmatory (positive samples) and specificity (negative samples) purposes. The comparative analyses demonstrated a good relationship between the semiquantitative analyses and GC/MS values.

Spiked sample Recovery

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

For the qualitative method, known levels of phencyclidine, spiked at levels less than or equal to minus 25% of the 25 ng/mL cutoff (0 – 18.75) and spiked levels greater than or equal to plus 25% of the 25 ng/mL cutoff (31.25 – 300) were consistently distinguished as negative or positive.

The semiquantitative results for known spiked concentrations for the Emit ® II Plus Phencyclidine quantitated within 10% of the nominal concentration between 8.0 ng/mL and 90 ng/mL.

Precision

A precision study was performed on the 25 ng/mL cut off level using the Emit® II Plus Phencyclidine Assay in both the qualitative and semi quantitative modes. Acceptable within 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 variations (%CV) for controls and cutoff (rates) at 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 cutoff (concentrations) ranged from 1.79 to 2.44% and total precision %CV ranged from 2.18 to 2.60%.

5. **Substantial Equivalence:**
In conclusion, Syva Company- Dade Behring Inc. considers the Emit® II Plus Phencyclidine Assay to be substantially equivalent to the Emit® II Phencyclidine 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: K993983
Trade Name: Emit® II Plus Phencyclidine Assay
Regulatory Class: II
Product Code: LCM
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.

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,

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

K993983

Device Name: Emit® II Plus Phencyclidine Assay

Indications for Use:

The Emit® II Plus Phencyclidine Assay is a homogeneous drugs-of-abuse enzyme immunoassay with a 25 ng/mL cutoff (SAMHSA initial test cutoff level). The assay is intended for use in the qualitative and semiquantitative analyses of phencyclidine in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Phencyclidine 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.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993983

(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)

Device Name: Emit® II Plus Phencyclidine Assay