K993987

JAN 2 7 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® II Plus Barbiturate Assay

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: 408-239-2000

2. **Device Classification Name:**
The Clinical Chemistry and Clinical Toxicology Devices Panel has classified "BarbiturateTest System" as Class II.

3. **Intended Use:**
The Emit® II Plus Barbiturate Assay is a drugs-of-abuse homogeneous enzyme immunoassay intended for use in the qualitative and semiquantitative analysis of barbiturates in the human urine. Emit® II assays are designed for use with a number of chemistry analyzers. The Emit® II Plus Barbiturate 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.

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 Barbiturate Assay is a drugs-of-abuse homogenous enzyme assay intended for use in the qualitative and semiquantitative analysis of barbiturates in human urine. The Emit® II Plus Barbiturate Assay has been found to be equivalent to the predicate device, Emit® II Barbiturate Assay, with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The Syva Emit® II Plus Barbiturate Assay showed excellent correlation to the Emit® II Barbiturate Assay (predicate method). The comparative analysis to the predicate method resulted in 94% agreement at the 200 ng/mL cutoff and 100% agreement at the 300ng/mL cutoff in finding samples negative and positive.

Spiked Sample Recovery: Analysis of spiked sample recovery by the qualitative mode of the Emit® II Plus Barbiturate Assay correctly identified the spiked specimens containing equal to or less than (<) minus (-) 25% of the 200 ng/mL secobarbital as negative and the spiked specimens containing equal to or greater than (>) plus (+) 25% of 200 ng/mL secobarbital as positive. The Emit® II Plus Barbiturate Assay also correctly identified the spiked specimens containing equal to or less than (<) minus (-) 25% of the 300 ng/mL secobarbital as negative and the spiked specimens containing equal to or greater than (>) plus (+) 25% of 300 ng/mL secobarbital as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Emit® II Plus Barbiturate Assay. Negative human urine specimens were spiked with concentrations of secobarbital at levels throughout the semiquantitative range of 200 to 800 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Barbiturate Assay. Within this range, recovery was within 99%-114% of nominal concentrations of spiked analyte.

Precision: A precision study was performed using Syva Emit® II Plus Barbiturate Assay in both the qualitative and semiquantitative modes. Acceptable within-run and total precision statistics for both the qualitative and semiquantitative modes of the assays were observed.

In the qualitative mode of the Emit® II Barbiturate Assay, the results demonstrated within-run precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 0.4 - 0.5% and total precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 0.6 – 0.7%.

In the semiquantitative mode of the assay the results demonstrated within-run precision with coefficients of variation (%CV) for controls and cutoff (concentrations) ranging from 1.0 – 3.8% and total precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 1.9-4.2%.

Sensitivity: The sensitivity level of the Emit® II Plus Barbiturate Assay is less than 20 ng/mL. This level represents the lowest concentration of secobarbital that can be distinguished from 0 ng/mL with a confidence level of 95%.

5. Substantial Equivalence:

In conclusion, Syva Company – Dade Behring Inc. considers the Syva Emit® II Plus Barbiturate Assay to be substantially equivalent to the Emit® II Barbiturate 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 2 7 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: K993987
Trade Name: Syva Emit® II Plus Barbiturate Assay
Regulatory Class: II
Product Code: KLT
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

K993987

Device Name: Syva Emit® II Plus Barbiturate Assay

Indications for Use:

The Emit® II Plus Barbiturate Assay is a drugs-of-abuse homogeneous enzyme immunoassay intended for use in the qualitative and semiquantitative analysis of barbiturates in the human urine. Emit® II assays are designed for use with a number of chemistry analyzers. The Emit® II Plus Barbiturate 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.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993987

(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)