FEB 1 2000

K993981

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

1. Manufacturer and Contact Information:

Manufacturer: Syva Company – Dade Behring Inc.
3403 Yerba Buena Rd.
P.O. Box 49013
San Jose, CA 95161-9013

Contact Information: Paul Rogers
Syva Company
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 have classified "Propoxyphene Test System" as Class II.

3. Intended Use:

Syva Emit® II Plus Propoxyphene Assay is a homogeneous enzyme immunoassay. The assay is intended for use in the qualitative and semiquantitative analysis of propoxyphene in human urine.

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 Syva Emit® II Plus Propoxyphene Assay is a homogenous enzyme assay intended for use in qualitative and semiquantitative analysis of propoxyphene in urine.

The Syva Emit® II Plus Propoxyphene Assay has been found to be equivalent to the predicate device: Syva Emit® II Propoxyphene Assay with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The Syva Emit® II Plus Propoxyphene Assay showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in 98% agreement in finding samples negative and positive.

Spiked Sample Recovery: In qualitative spike analysis, the Emit® II Plus Propoxyphene Assay using a 300 ng/mL cutoff correctly identified the spiked specimens as being negative and positive. Known levels of propoxyphene, spiked at levels less than or equal to minus 25% of the cutoff (0 to 225 ng/mL) were consistently distinguished as negative and those spiked at levels greater than or equal to plus 25% of the cutoff (375 to 1500 ng/mL) were consistently distinguished as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Emit® II Plus Propoxyphene Assay. Negative human urine specimens were spiked with concentrations of propoxyphene at levels throughout the semiquantitative range of 75 to 450 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Propoxyphene Assay. Within this range, recovery ranged up to ± 13% of nominal concentrations of spiked analyte.

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

Qualitative results, determined from rates for controls and cutoff calibrator, demonstrated within-run precision with coefficients of variation (CV) of 0.4% and total precision with CV ranging from 0.7 – 0.8%.

Semiquantitative results, determined from concentrations for controls and cutoff calibrator, demonstrated within-run precision with CV ranging from 1.6 – 2.2% and total precision with CV ranging from 3.0 – 3.8%.

Sensitivity: The sensitivity level of the Emit® II Plus Propoxyphene Assay is less than 60 ng/mL. This level represents the lowest concentration of propoxyphene 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 Propoxyphene Assay to be substantially equivalent to the Emit® II Propoxyphene 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

FEB 1 2000

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

Re: K993981
Trade Name: Syva Emit® II Plus Propoxyphene Assay
Regulatory Class: II
Product Code: JXN
Dated: November 23, 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

Device Name: Syva Emit® II Plus Propoxyphene Assay

Indications for Use:

The Emit® II Plus Propoxyphene Assay is a homogeneous drugs-of-abuse enzyme immunoassay with a 300 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of propoxyphene in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Propoxyphene 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

P.Bleinfeldt for Dr. J. Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K992981

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)