K994005

JAN 2 0 2000

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

1. Manufacturer and Contact Information:

Manufacturer: Syva Company–Dade Behring Inc.
20400 Mariani Ave.
San Jose, 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:

"Methadone Test Systems" is a Class II device (21 CFR 862.3620, revised April 1, 1998)

3. Intended Use:

The Syva Emit® II Plus Methadone Assay is a homogeneous enzyme immunoassay with 150 ng/mL or 300 ng/mL cutoffs. The assay is intended for use in the qualitative and semiquantitative analyses of methadone 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 Methadone Assay is a homogenous enzyme assay intended for use in qualitative and semiquantitative analysis of methadone in human urine.

The Syva Emit® II Plus Methadone Assay has been found to be equivalent to the predicate device, Syva Emit® II Methadone Assay with regard to analyte detected, intended use, and performance characteristics.

Comparative Analysis: The Syva Emit® II Plus Methadone Assay showed excellent correlation for qualitative analyses. With the 150 ng/mL cutoff, the Syva Emit® II Plus Methadone Assay resulted in 95 % agreement with the reference method, GC/MS, in finding specimens negative and positive. With the 300 ng/mL cutoff, comparative analysis of the Syva Emit® II Plus Methadone Assay to the predicate resulted in 100 % agreement in finding samples negative and positive.

Spiked-Sample Recovery: In qualitative analysis, the Syva Emit® II Plus Methadone Assay correctly identified the spiked specimens as containing methadone either less than or greater than the dual cutoffs, 150 ng/mL or 300 ng/mL. With the 150 ng/mL cutoff, known levels of methadone, spiked at levels less than or equal to minus 25 % of the cutoff (0 to 112.5 ng/mL) and spiked at levels greater than or equal to plus 25 % of the cutoff (187.5 to 1500 ng/mL), were consistently distinguished as negative or positive. With the 300 ng/mL cutoff, known levels of methadone, spiked at levels less than or equal to minus 25 % of the cutoff (0 to 225 ng/mL) and spiked at levels greater than or equal to plus 25 % of the cutoff (375 to 3000 ng/mL), were consistently distinguished as negative or positive.

The semiquantitative use was assessed by determining the accuracy of recovery for the analyte-spiked samples by the Syva Emit® II Plus Methadone Assay. Negative human urine was spiked with concentrations of methadone at levels throughout the semiquantitative ranges of 50 to 450 ng/mL (150 ng/mL cutoff) and 112.5 to 900 ng/mL (300 ng/mL cutoff). For each known concentration, drug recovery was calculated using the average concentration obtained by the Syva Emit® II Plus Methadone Assay. Within the semiquantitative range for the 150 ng/mL cutoff, recovery was within ± 13 % of the nominal concentrations of spiked analyte. Within the semiquantitative range for the 300 ng/mL cutoff, recovery was ± 20 % of the nominal concentrations of spiked analyte.

Precision: The Syva Emit® II Plus Methadone Assay was analyzed for precision in both qualitative (rates) and semiquantitative (concentration) modes for each cutoff. For both modes, acceptable within-run and total precision statistics, coefficients of variation (CV), were observed.

Qualitative results at the 150 ng/mL cutoff, determined from rates for controls and cutoff calibrator, gave values for within-run precision CV ranging from 0.5 to 0.7 % and values for total precision CV ranging from 1.2 to 1.7 %. Qualitative results at the 300 ng/mL cutoff, determined from rates for controls and cutoff calibrator, gave values for within-run precision CV ranging from 0.6 to 0.7 % and values for total precision CV ranging from 1.5 to 2.1 %.

Semiquantitative results at the 150 ng/mL cutoff, determined from concentrations for controls and cutoff calibrator, gave values for within-run precision CV of 1.0 % and values for total precision CV ranging from 2.3 to 3.0 %. Semiquantitative results at the 300 ng/mL cutoff, determined from concentrations for controls and cutoff calibrator, gave values for within-run precision CV ranging from 0.9 to 1.1 % and values for total precision CV ranging from 1.6 to 3.7 %.

Sensitivity: The sensitivity level of the Syva Emit® II Plus Methadone Assay is less than 10 ng/mL at the 150 ng/mL cutoff and is less than 20 ng/mL at the 300 ng/mL cutoff. This sensitivity level represents the lowest concentration of methadone 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 Methadone Assay to be substantially equivalent to the Syva Emit® II Methadone Assay with regard to analyte detected, intended use, and performance characteristics.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

For Emit® II Plus Cannabinoid 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 "Cannabinoid Test System" as Class II.

3. Intended Use:

The Emit® II Plus Cannabinoid Assay is a homogeneous enzyme immunoassay with a 20 ng/mL, 50 ng/mL (SAMHSA initial test cutoff level), or 100 ng/mL cutoff. The assay is intended for use in the qualitative and semiquantitative analyses of cannabinoids in human urine. Emit® II Plus assays are designed for use with a number of chemistry analyzers.

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 Cannabinoid Assay is a drugs-of-abuse homogenous enzyme assay intended for use in the qualitative and semiquantitative analysis of Cannabinoids in human urine. The Emit® II Plus Cannabinoid Assay has been found to be equivalent to the predicate devices, Emit® II Cannabinoid Assays, 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 0 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: K994005
Trade Name: Syva Emit® II Plus Methadone Assay
Regulatory Class: II
Product Code: DJR
Dated: November 22, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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

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.

510(k) Number (If known): K994005

Device Name: Syva Emit® II Plus Methadone Assay

Indications for Use:

The Emit® II Plus Methadone 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 methadone in human urine. The Emit® II Plus assays are designed for use with a number of chemistry analyzers.

The Emit® II Plus Methadone 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.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994005

(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)