K993984

JAN 18 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

For Syva Emit® II Plus Cannabinoid Assay

20 ng/mL Protocol

Comparative Analysis: The Syva Emit® II Plus Cannabinoid Assay showed excellent correlation to the Emit® II Cannabinoid 20 ng Assay (predicate method). The comparative analysis to the predicate method resulted in 100% agreement in finding samples negative and positive.

Spiked Sample Recovery: Analysis of spiked sample recovery by the qualitative mode of the Emit® II Plus Cannabinoid Assay correctly identified the spiked specimens containing equal to or less than (<) minus (-) 25% of the 20 ng/mL cutoff as negative and the spiked specimens containing equal to or greater than (>) plus (+) 25% of 20 ng/mL cutoff as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Emit® II Plus Cannabinoid Assay. Negative human urine specimens were spiked with concentrations of cannabinoids (THC) at levels throughout the semiquantitative range of 15 to 55 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Cannabinoid Assay. Within this range, recovery was within 79%-106% of nominal concentrations of spiked analyte.

Precision: A precision study was performed using Syva Emit® II Plus Cannabinoid 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 Cannabinoid Assay, the results demonstrated within-run precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 0.5 - 0.8% and total precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 1.4 – 2.6%.

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 1.8 – 2.3% and total precision with coefficients of variation (%CV) for controls and cutoff (concentration) ranging from 4.9 – 6.7%.

Sensitivity: The sensitivity level of the Emit® II Plus Cannabinoid Assay is less than 10 ng/mL. This level represents the lowest concentration of 11-nor-Δ^9-THC-9-carboxylic acid that can be distinguished from 0 ng/mL with a confidence level of 95%.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

For Syva Emit® II Plus Cannabinoid Assay (cont.)

50 ng/mL Protocol

Comparative Analysis: The Syva Emit® II Plus Cannabinoid Assay showed excellent correlation to the Emit® II Cannabinoid 50 ng Assay (predicate method). The comparative analysis to the predicate method resulted in 100% agreement in finding samples negative and positive.

Spiked Sample Recovery: Analysis of spiked sample recovery by the qualitative mode of the Emit® II Plus Cannabinoid Assay correctly identified the spiked specimens containing equal to or less than (<) minus (-) 25% of the 50 ng/mL cutoff as negative and the spiked specimens containing equal to or greater than (>) plus (+) 25% of 50 ng/mL cutoff as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Emit® II Plus cannabinoid (THC) Assay. Negative human urine specimens were spiked with concentrations of Cannabinoids at levels throughout the semiquantitative range of 25 to 180 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Cannabinoid Assay. Within this range, recovery was within 86%-118% of nominal concentrations of spiked analyte.

Precision: A precision study was performed using Syva Emit® II Plus Cannabinoid 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 Cannabinoid Assay, the results demonstrated within-run precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 0.6 - 0.7% and total precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 1.4 – 2.1%.

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 1.3 – 1.5% and total precision with coefficients of variation (%CV) for controls and cutoff (concentration) ranging from 2.8 – 5.4%.

Sensitivity: The sensitivity level of the Emit® II Plus Cannabinoid Assay is less than 15 ng/mL. This level represents the lowest concentration of 11-nor-Δ^9-THC-9-carboxylic acid that can be distinguished from 0 ng/mL with a confidence level of 95%.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

For Syva Emit® II Plus Cannabinoid Assay (cont.)

100 ng/mL Protocol

Comparative Analysis: The Syva Emit® II Plus Cannabinoid Assay showed excellent correlation to the Emit® II Cannabinoid 100 ng Assay (predicate method). The comparative analysis to the predicate method resulted in 99% agreement in finding samples negative and positive.

Spiked Sample Recovery: Analysis of spiked sample recovery by the qualitative mode of the Emit® II Plus Cannabinoid Assay correctly identified the spiked specimens containing equal to or less than (<) minus (-) 25% of the 100 ng/mL cutoff as negative and the spiked specimens containing equal to or greater than (>) plus (+) 25% of 100 ng/mL cutoff as positive.

The semiquantitative attribute was assessed by determining the accuracy of recovery for analyte-spiked samples by the Emit® II Plus Cannabinoid Assay. Negative human urine specimens were spiked with concentrations of Cannabinoids at levels throughout the semiquantitative range of 15 to 180 ng/mL. For each known concentration, drug recovery was calculated using the average concentration obtained by the Emit® II Plus Cannabinoid Assay. Within this range, recovery was within 80%-106% of nominal concentrations of spiked analyte.

Precision: A precision study was performed using Syva Emit® II Plus Cannabinoid 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 Cannabinoid Assay, the results demonstrated within-run precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 0.6 - 0.7% and total precision with coefficients of variation (%CV) for controls and cutoff (rates) ranging from 1.4 – 2.0%.

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 2.1 – 2.7% and total precision with coefficients of variation (%CV) for controls and cutoff (concentration) ranging from 6.0 – 7.4%.

Sensitivity: The sensitivity level of the Emit® II Plus Cannabinoid Assay is less than 10 ng/mL. This level represents the lowest concentration of 11-nor-Δ^9-THC-9-carboxylic acid 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 Cannabinoid Assay to be substantially equivalent to the Emit® II Cannabinoid 20 ng Assay, the Emit® II Cannabinoid 50 ng Assay, and the Emit® II Cannabinoid 100 ng 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 18 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: K993984
Trade Name: Syva Emit® II Plus Cannabinoid Assay
Regulatory Class: II
Product Code: LDJ
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.

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
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993984

Device Name: Emit® II Plus Cannabinoid Assay

Indications for Use:

The Emit® II Plus Cannabinoid Assay is a homogeneous drugs-of-abuse 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.

Jean Cooper

(Division Sign-Off)
Division ...
510(k) ... K993984

(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 Cannabinoid Assay