K993980

FEB 1 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® Ethyl Alcohol Assay

1. **Manufacturer and Contact Information:**

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

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 have classified "Ethyl Alcohol System" as Class II.

3. **Intended Use:**
Emit® II Plus Ethyl Alcohol Assay is an enzyme assay. The assay is intended for use in the quantitative analysis of ethyl alcohol in human serum or plasma.

4. **Device Description and Characteristics:**
This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Syva Company - Dade Behring Inc. is submitting the Premarket Notification, 510(k) with the intention to commercially market an *in vitro* diagnostic reagent test kit for the analysis of ethyl alcohol in human urine, serum, or plasma.

The Syva Emit® II Plus Ethyl Alcohol Assay is an enzyme assay intended for use in quantitative analysis of ethyl alcohol in human urine, serum, or plasma. The Syva Emit® II Plus Ethyl Alcohol Assay has been found to be equivalent to the predicate device: Emit® Ethyl Alcohol Assay (K903153) with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The Syva Emit® II Plus Ethyl Alcohol Assay showed excellent correlation to the predicate method. The comparative analysis to the predicate method resulted in a correlation of 0.986 with serum and 0.997 with urine, with a slope value of 1.000 with both urine and serum.

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For Emit® Ethyl Alcohol Assay (cont.)

Precision: A Precision study was performed and the Syva Emit® II Plus Ethyl Alcohol Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) ranging from 1.39% to 1.55% and acceptable total precision with coefficients of variation (%CV) ranging from 1.61% to 1.78%.

Specificity: A study was performed on potentially cross-reacting compounds and the Syva Emit® II Plus Ethyl Alcohol Assay demonstrated acceptable levels of cross-reactivity, ranging from <0.1 – 14.2%.

Sensitivity: The sensitivity level of the Emit® II Plus Ethyl Alcohol Assay is less than 3.0 mg/dL. This level represents the lowest concentration of amphetamines that can be distinguished from 0 ng/mL with a confidence level of 95%.

Endogenous Interference: Endogenous interference in serum, due to either bilirubin, hemoglobin, or trigycerides, in the Syva Emit® II Plus Ethyl Alcohol Assay are 99, 100, and 97% recovery compared to controls. The presence of LDH/Lactate does not cause a significant interference in the Syva Emit® II Plus Ethyl Alcohol Assay (0.4 mg/dL).
A series of potentially interfering endogenous substances in urine were tested by the Syva Emit® II Plus Ethyl Alcohol Assay. The recoveries for the interfering substances range from 99 – 104%.

Spiked Sample Recovery: Spike recovery of ethanol in human serum and urine by the Syva Emit® II Plus Ethyl Alcohol Assay was performed across the quantitative range of between 10 and 600 mg/dL. Recovery of ethanol spikes ranged between 95.7 – 101.5%.

High Sample Dilution: Dilution of high serum and urine samples by water the Negative Calibrator were performed in the Syva Emit® II Plus Ethyl Alcohol Assay. Recovery from the normal concentrations in both types of samples diluted with either water or Negative Calibrator ranged from 97.1 – 100.9%.

Anticoagulants: The performance of the anticoagulants EDTA (K_3), Sodium Citrate, Sodium Heparin, and Oxalate/Fluoride, as compared to serum, was assayed by the Syva Emit® II Plus Ethyl Alcohol Assay. Average recovery versus the serum control ranged from95.5 – 102.3%.

Linearity: The linearity of diluted serum and urine samples were tested in the Syva Emit® II Plus Ethyl Alcohol Assay. Both serum and urine samples are considered linear according to the acceptance criteria of the CAP linearity survey.

Urine Preservatives: the effect of urine preservatives was tested by the Syva Emit® II Plus Ethyl Alcohol Assay. Recoveries of urine preservatives compared to controls ranged from 97.5 – 99.1%.

Calibration Stability: The calibration stability of the Syva Emit® II Plus Ethyl Alcohol Assay on the SYVA- 30R Biochemical System was determined to be 25 days.

5. **Substantial Equivalence:**
In conclusion, Syva Company considers the Emit® II Plus Ethyl Alcohol Assay to be substantially equivalent to the Emit® Ethyl Alcohol Assay (K903153) 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: K993980
Trade Name: Emit® II Plus Ethyl Alcohol Assay
Regulatory Class: II
Product Code: DML
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

510(k) Number (If known):

Device Name: Emit® II Plus Ethyl Alcohol Assay

Indications for Use:

The Emit® II Plus Ethyl Alcohol Assay is an enzyme assay intended for use in the quantitative analysis of ethyl alcohol (ethanol) in human urine, plasma, and serum. The Emit® II Plus Ethyl Alcohol Assay is designed for use with most clinical chemistry analyzers.

(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 Ethyl Alcohol Assay

Patricia Bernhardt for Dr. D. Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993980