K984232

JAN 22 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
For Emit® d.a.u.™ Opiates 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
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 "Opiate Test System" as Class II. Reference: 21 CFR 862.3650, revised April 1, 1993.

3. **Intended Use:**
Emit® d.a.u.™ Opiates Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 2000 ng/mL cutoff. The assay is intended for use in the qualitative or semiquantitative analysis of opiates 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.

Syva Company is submitting the Premarket Notification, 510(k) to convey our intention to commercially distribute the modified Emit® d.a.u.™ Opiates Assay, an *in vitro* diagnostic reagent test kit for the qualitative or semiquantitative (Emit® d.a.u.™ Opiates Assay at 300 ng/mL only) analysis of Opiates in human urine. The modified Emit® d.a.u.™ Opiates Assay is a homogenous enzyme assay with a 300 ng/mL or 2000 ng/mL cutoff. The modified Emit® d.a.u.™ Opiates Assay has been found to be equivalent to the predicate device: Emit® II Opiates 300/2000 Assay (K971596) with regard to intended use, assay sample, and overall performance characteristics.

Comparative Analysis: The modified Emit® d.a.u.™ Opiates Assay, utilizing the 2000 ng/mL cutoff, correctly distinguished spiked samples as positive or negative relative to the cutoff. The comparative analysis to the predicate method showed 100% agreement for positive specimens and 97% agreement for negative samples.

Precision: A Precision study was performed utilizing the 2000 ng/mL (qualitative) cutoff, the modified Emit® d.a.u.™ Opiates Assay demonstrated acceptable within-run precision with coefficients of variation (%CV) as rates ranging from 0.84 to 1.18% and acceptable total precision with coefficients of variation (%CV) as rates ranging from 1.55 to 2.59%.

5. **Substantial Equivalence:**
In conclusion, Syva Company considers the modified Emit® d.a.u.™ Opiates Assay to be substantially equivalent to the Emit® II Opiates 300/2000 Assay (K971576) with regard to intended use, assay sample, and overall performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 22 1999

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

Re: K984232
Trade Name: Emit® d.a.u.™ Opiate Assay
Regulatory Class: II
Product Code: DJG
Dated: November 23, 1998
Received: November 25, 1998

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):

Device Name: Emit® d.a.u.™ Opiates Assay

Indications for Use:

Emit® d.a.u.™ Opiates Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 2000 ng/mL cutoff. The assay is intended for use in the qualitative or semiquantitative analysis of opiates in human urine. The assay is used to screen for potential drugs of abuse.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984732

(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)