K011289

MAY 1 5 2001

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

1. **Manufacturer and Contact Information:**

Manufacturer: Syva Company – Dade Behring Inc.
20400 Mariani Ave.
Cupertino, CA 95014

Contact Information: Susan L. Collins
Regulatory Affairs
Syva Company – Dade Behring, Inc.
3403 Yerba Buena Road
San Jose, CA 95135
Tel: 408 – 239 - 4412
Fax: 408 – 239 – 2348

2. **Date Summary Prepared:**
April 26, 2001

3. **Device Trade Name:**
Emit® II Plus Opiate Assay

4. **Common Name:**
Enzyme Immunoassay, Opiate

5. **Device Classification Name:**
The Clinical Chemistry and Clinical Toxicology Devices Panel have classified "Opiate test system" as Class II, 21 CFR Part 862. 3650.

6. **Intended Use:**
The Emit® II Plus Opiate 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 and semi-quantitative analysis of opiates in human urine. These reagents are packaged specifically for use on a variety of Olympus® analyzers.

7. **Device Description:**
The modified assay is similar to the predicate device with minor differences in the packaging of the product. The modified assay has a smaller fill volume of the reagents into different shaped (wedge) reagent bottles. Both the predicate and modified device reagent bottles are made of the same material (HDPE). The modified reagent bottles incorporate a barcode label with assay specific information and are compatible with the Olympus® AU400/600, AU800/1000 and AU2700 Series Analyzers. Reagent 1 and 2 of the modified assay contains BSA and no bulking agents, in comparison to the predicate device.

8. **Substantial Equivalence**

The modified device has the same operating principles, design, manufacturing materials, method of manufacture, assay performance characteristics and intended use as the predicate device. In conclusion the modified Emit® II Plus Opiate Assay is substantially equivalent to the predicate Emit® II Opiates 300/2000 Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Susan L. Collins
Regulatory Affairs
Syva Company-Dade Behring Inc.
3403 Yerba Buena Road
San Jose, CA 95135

Re: 510(k) Number: K011289
Trade/Device Name: Emit® II Plus Opiate Assay
Regulation Number: 862.3650
Regulatory Class: II
Product Code: DJG
Dated: April 26, 2001
Received: April 27, 2001

Dear Ms. Collins:

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

Indications for Use Statement

510(k) Number (if known): **Device Name:** Emit® II Plus Opiate Assay

Indications for Use:

The Emit® II Plus Opiate 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 and semi-quantitative analysis of opiates in human urine. These reagents are packaged specifically for use on a variety of Olympus® analyzers.

The Emit® II Plus Opiate 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.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 011289

(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)