K971600

BEHRING

JUN 25 1997

3403 Yerba Buena Road
San Jose. CA 95135

SUMMARY OF SAFETY AND EFFECTIVENESS

Emit® Calibrator B Level 1 (cutoff)
Emit® Calibrator B Level 2 (high)

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

Behring Diagnostics Inc. is submitting this Premarket Notification, 510(k) to convey our intention to manufacture for commercial distribution a modified Emit® Calibrator B Level 1 (cutoff) and a modified Emit® Calibrator B Level 2 (high) used in the calibration of the Emit® d.a.u.™ Amphetamine Class, Barbiturate (300 ng/mL cutoff), Benzodiazepine (300 ng/mL cutoff), Cocaine Metabolite (150 ng/mL cutoff), Methadone, Methaqualone, and Propoxyphene Assays. Emit® Calibrator B Level 1 (cutoff) and Emit® Calibrator B Level 2 (high) are also used in the calibration of the Emit® II Barbiturate (300 ng/mL cutoff), Benzodiazepine (300 ng/mL cutoff), Methadone, Methaqualone, Opiates 300/2000, and Propoxyphene Assays.

The modified Emit® Calibrator B Level 1 (cutoff) and Emit® Calibrator B Level 2 (high) are substantially equivalent to the currently marketed Emit® Calibrator B Level 1 (cutoff) and Emit® Calibrator B Level 2 (high) (K912729) with regard to intended use and overall performance characteristics. The most significant difference between the modified Emit® Calibrator B Level 1 (cutoff) and Emit® Calibrator B Level 2 (high) is the addition of morphine at 2000 ng/mL in the Calibrator B Level 1 (cutoff) and morphine at 4000 ng/mL in the Calibrator B Level 2 (high).

The modified Calibrators B contain the following drug concentrations:

	Level 1 (ng/mL)	Level 2 (ng/mL)
Benzoylecgonine	150	3000
d-Amphetamine	300	2000
Methadone	300	1000
Methaqualone	300	1500
Morphine	2000	4000
Oxazepam	300	1000
Propoxyphene	300	1000
Secobarbital	300	1000

In conclusion, Behring Diagnostics Inc. considers the modified Emit® Calibrator B Level 1 (cutoff) and the modified Emit® Calibrator B Level 2 (high) to be substantially equivalent to the existing Emit® Calibrator B Level 1 (cutoff) and Emit® Calibrator B Level 2 (high).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 1997

David Kolesar
Administrator, Regulatory Affairs
Behring Diagnostics
P.O. Box 49013
San Jose, California 95161-9013

Re: K971600
Emit® Calibrator B Level 1 (Cutoff)/Emit® Calibrator B Level 2 (High)
Regulatory Class: II
Product Code: DKB
Dated: April 29, 1997
Received: May 1, 1997

Dear Mr. Kolesar:

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 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.

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/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® Calibrator B Level 1 (cuttof)

Emit® Calibrator B Level 2 (high)

Indications For Use:

The Emit® Calibrator B Level 1 and Calibrator B Level 2 are used in the calibration of the Emit® d.a.u.™ Amphetamine Class, Barbiturate (300 ng/mL cutoff), Benzodiazepine (300 ng/mL cutoff), Cocaine Metabolite (150 ng/mL cutoff), Methadone, Methaqualone, and Propoxyphene Assays. The Emit® Calibrator B Level 1 and Calibrator B Level 2 are also used in the calibration of the Emit® II Barbiturate (300 ng/mL cutoff), Benzodiazepine (300 ng/mL cutoff), Methadone, Methaqualone, Opiates 300/2000, and Propoxyphene Assays.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K97/600