K971596

JUN 25 1997

BEHRING

3403 Yerba Buena Road
P.O. Box 49031
San Jose, CA. 95161-9013

SUMMARY OF SAFETY AND EFFECTIVENESS
Emit® II Opiates 300/2000Assay

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 commericially distribute the Emit® II Opiates 300/2000 Assay, an in vitro diagnostic reagent test kit for the qualitative and semiquantitative analysis of Opiates in human urine. The Emit® II Opiates 300/2000 Assay is a homogeneous enzyme immunoassay with a 300 ng/mL or 2000 ng/mL cutoff. The Emit® II Opiates 300/2000 Assay has been found to be substantially equivalent to the predicate device: Emit® II Opiate Assay (K902577) with regard to intended use, assay sample, and overall performance characteristics.

PERFORMANCE STUDIES

Qualitatively, utilizing the 300 ng/mL cutoff, the Emit® II Opiates 300/2000 Assay demonstrated acceptable within-run precision with coefficients of variation (CV%) as rates ranging from 0.49 - 0.79% and acceptable total precision with coefficients of variation (CV%) as rates ranging from 0.66 - 0.85%. Utilizing the 2000 ng/mL cutoff, the Emit® II Opiates 300/2000 Assay demonstrated acceptable within-run precision with coefficients of variation (CV%) as rates ranging from 0.66 - 0.99% and acceptable total precision with coefficients of variation (CV%) as rates ranging from 0.78 - 1.11% The Emit® II Opiates 300/2000 Assay using the either the 300 ng/mL cutoff or the 2000 ng/mL cutoff correctly distinguished spiked samples as positive or negative relative to its respective cutoff. Comparative analysis to the predicate method (99.4% agreement) and GC/MS confirmation (95.3% agreement) are excellent.

Semiquantitatively, utilizing the 300 ng/mL cutoff, the Emit® II Opiates 330/2000 Assay demonstrated acceptable within-run precision with coefficients of variation (CV%) as concentrations ranging from 2.66 - 4.30% and acceptable total precision with coefficients of variation (CV%) as concentrations ranging from 3.63 - 5.66%. Utilizing the 2000 ng/mL cutoff, the Emit® II Opiates 300/2000 Assay demonstrated acceptable within-run precision with coefficients of variation (CV%) as concentrations ranging from 2.49 - 3.33% and acceptable total precision with coefficients of variation (CV%) as concentrations ranging from 3.74 - 4.65%%. The Emit® II Opiates 300/2000 Assay, encompassing the either the 300 ng/mL cutoff or the 2000 ng/mL cutoff, quantitated spiked samples within 20% of the mean GC/MS value. Comparative analysis to GC/MS on the basis of concentrations and confirmation of the Emit assay results are excellent.

In conclusion, Behring Diagnostics Inc. considers the Emit® II Opiates 300/2000 Assay to be substantially equivalent to the Emit® II Opiate Assay (K902577).

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: K971596
Emit® II Opiates 300/2000 Assay
Regulatory Class: II
Product Code: DJG
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® II Opiates 300/2000 Assay

Indications For Use:

The Emit® II Opiates 300/2000 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 semiquantitative analysis of opiates in human urine.

(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_____

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971596

Attachments