OCT 2 8 2004

510(k) Summary
Emit® Caffeine Assay

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K042407

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer:	Dade Behring Inc. 20400 Mariani Ave. Cupertino, CA 95014
Contact Information:	Dade Behring Inc. P.O. Box 6101 Newark, DE 19714 Attn: Yuk-Ting Lewis Tel: 302-631-7626
Date of Preparation:	October 18, 2004

2. Device Name / Classification

Emit® Caffeine Assay / Enzyme immunoassay, Theophylline

Product code: 91 KLS

3. Identification of the Legally Marketed Device

Emit® Caffeine Assay – K853872

4. Device Description

The Emit® Caffeine Assay is a homogeneous enzyme immunoassay technique used for the analysis of specific compounds in biological fluids. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate deyhdrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that can be measured spectrophotometrically.

Endogenous serum G6PDH does not interfere because the coenzyme functions only with the bacterial (*Leuconostoc mesenteroides*) enzyme employed in the assay.

5. Device Intended Use

The Emit® Caffeine Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of caffeine levels in human serum in subjects undergoing therapy with caffeine, especially in cases of neonatal apnea.

6. Medical device to which equivalence is claimed and comparison information

The modified Emit® Caffeine Assay has a broader intended use than the currently cleared Emit® Caffeine Assay to include measurement of caffeine as a parent drug.

The use of the current Emit® Caffeine Assay is limited to measurement of caffeine as a metabolite of Theophylline.

To support the broader intended use, a method comparison study was performed using 110 neonate samples with values spanning the assay range. Of these samples, thirty-one (31) were from patients who had received Theophylline and 79 were from patients who had received with Caffeine. The Assay results were compared to HPLC. The Emit® Caffeine Assay had excellent correlation with HPLC (correlation coefficient=0.99).

Other performance characteristics of the Emit® Caffeine Assay were previously established under K853872.

The Emit® Caffeine Assay, with broader intended use, is substantially equivalent to the current Emit® Caffeine Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 8 2004

Ms. Yuk-Ting Lewis
Regulatory Affairs and Compliance Manager
Dade Behring, Inc
PO Box 6101
M/S 514
Newark, DE 19714

Re: k042407
Trade/Device Name: Emit® Caffeine Assay
Regulation Number: 21 CFR 862.3880
Regulation Name: Theophylline test system
Regulatory Class: Class II
Product Code: KLS
Dated: September 1, 2004
Received: September 3, 2004

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Emit® Caffeine Assay

Indications For Use:

The Emit® Caffeine Assay is a homogeneous enzyme immunoassay intended for use in the quantitative analysis of caffeine levels in human serum in subjects undergoing therapy with caffeine, especially in cases of neonatal apnea.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042407