APR 6 2006

K060385



# 510(k) Summary
# Emit® 2000 Tacrolimus Assay
# Emit® 2000 Tacrolimus Sample Pretreatment Reagent

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

The assigned 510(k) number is: _____

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

| | |
|---|---|
| Manufacturer: | Dade Behring Inc.<br>20400 Mariani Ave.<br>Cupertino, CA 95014 |
| Contact Information: | Dade Behring Inc.<br>P.O. Box 6101<br>Newark, DE 19714<br>Attn: Yuk-Ting Lewis<br>Tel: 302-631-7626 |
| Date of Preparation: | February 7, 2006 |

## 2. Device Name / Classification

Emit® 2000 Tacrolimus Assay / Class II
Emit® 2000 Tacrolimus Sample Pretreatment Reagent / Class II

## 3. Identification of the Predicate Device

Abbott IMx® Tacrolimus II Assay and Pretreatment Reagent, P970007
(Note: Tacrolimus test systems have been reclassified into Class II since the predicate was approved.)

## 4. Device Description

The Emit® 2000 Tacrolimus Assay is for in vitro diagnostic use for the quantitative analysis of tacrolimus and metabolite in human whole blood as an aid in the management of tacrolimus therapy in liver and kidney transplant patients. The Emit® 2000 Tacrolimus Assay is comprised of an antibody reagent, a buffer reagent and an enzyme reagent. This assay contains mouse monoclonal antibodies with a high specificity for tacrolimus.

The Emit® 2000 Tacrolimus Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Tacrolimus Assay. The Emit® 2000 Tacrolimus Sample Pretreatment Reagent is used to pretreat the whole blood samples, calibrators, and controls prior to testing with the Emit® 2000 Tacrolimus Assay. The pretreatment process lyses the cells, extracts the tacrolimus, and precipitates most of the blood proteins. The pretreated samples are centrifuged, and an aliquot of the resulting supernatant containing tacrolimus is then assayed using the Emit® 2000 Tacrolimus Assay.

## 5. Device Intended Use

The Emit® 2000 Tacrolimus Assay is for in vitro quantitative analysis of tacrolimus and metabolite in human whole blood as an aid in the management of tacrolimus therapy in liver and kidney transplant patients.

The Emit® 2000 Tacrolimus Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Tacrolimus Assay.

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

The Emit® 2000 Tacrolimus Assay and EMIT® 2000 Pretreatment Reagent are substantially equivalent in intended use and technological characteristics to the Abbott IMx® Tacrolimus II Assay and Pretreatment Reagent. Both devices are immunoassays intended for use in the quantitative measurement of tacrolimus in human whole blood. Both devices require a manual pretreatment. The Emit® 2000 Tacrolimus Assay has an assay range of 2-30 ng/mL. The Abbott IMx Tacrolimus II Assay has an assay range of 1.5-30 ng/mL.

Comparison Information

Method comparison studies were conducted at two external sites comparing the Emit® 2000 Tacrolimus Assay against two predicates:

- liquid chromatography / mass spectrometry (LC/MS) and
- Abbott IMx® Tacrolimus II Assay.

Samples from 2 transplant groups (liver and kidney) were included in the studies. The data from both sites were pooled and analyzed by linear regression.

| Comparative Method<br>LC/MS/MS | Slope | Intercept | r | n |
|---|---|---|---|---|
| All samples | 1.15 | -0.33 | 0.940 | 197 |
| Kidney | 1.10 | -0.12 | 0.899 | 90 |
| Liver | 1.01 | 0.35 | 0.946 | 65 |
| Abbott IMx® Tacrolimus II Assay | | | | |
| All samples | 0.92 | -0.04 | 0.881 | 192 |
| Kidney | 0.79 | 0.87 | 0.863 | 88 |
| Liver | 0.83 | 0.69 | 0.812 | 62 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 6 2006

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

Re: k060385
Trade/Device Name: Emit®2000 Tacrolimus Assay
Emit®2000 Tacrolimus Sample Pretreatment Reagent
Regulation Number: 21 CFR§ 862.1678
Regulation Name: Tacrolimus test system
Regulatory Class: Class II
Product Code: MLM
Dated: February 10, 2006
Received: February 14, 2006

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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):** K060385

**Device Name:** **Emit® 2000 Tacrolimus Assay**
**Emit® 2000 Tacrolimus Sample Pretreatment Reagent**

**Indications For Use:**

The Emit® 2000 Tacrolimus Assay is for in vitro quantitative analysis of tacrolimus and metabolite in human whole blood as an aid in the management of tacrolimus therapy in liver and kidney transplant patients.

The Emit® 2000 Tacrolimus Sample Pretreatment Reagent is an accessory reagent for use with the Emit® 2000 Tacrolimus Assay.

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)

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



[illegible] In Vitro Diagnostic Device
[illegible]ation and Safety

K060385