

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k060371

B. Purpose for Submission:

New Device

C. Measurand:

Tacrolimus

D. Type of Test:

Calibrator materials for tacrolimus

E. Applicant:

DADE BEHRING, INC.

F. Proprietary and Established Names:

Emit® 2000 Tacrolimus Calibrators

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT	II	21 CFR 862.1150	75

H. Intended Use:

- Intended use(s):
The Emit® 2000 Tacrolimus Calibrators are intended for use as a reference in measuring tacrolimus in human whole blood using the Emit® 2000 Tacrolimus Assay.
- Indication(s) for use:
The Emit® 2000 Tacrolimus Calibrators are intended for use as a reference in measuring tacrolimus in human whole blood using the Emit® 2000 Tacrolimus Assay
- Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

Not Applicable (N/A)

I. Device Description:

The calibrators contain tacrolimus in preserved whole blood hemolysate. The calibrator kit consists of one vial of each calibrator level with target concentrations of 0, 2.5, 5, 10, 20, and 30 ng/mL of tacrolimus.

The calibrators contain human blood components. Each lot was tested and found to be non-reactive for Hepatitis B Surface Antigen (HBsAg), Antibody to Human Immunodeficiency Virus (HIV 1/2), Antibody to Hepatitis C Virus (HCV) and Antibody to Syphilis.

J. Substantial Equivalence Information:

Predicate	Abbott IMx Tacrolimus II Calibrator, P970007
Describe the item being compared	
The Abbott IMx Tacrolimus II Calibrators are for use in calibrating the Abbott IMx Tacrolimus II Assay. The Abbott Calibrators are prepared in preserved human whole blood with preservatives. There are 6 calibrator levels with nominal values of 0, 3, 6, 12, 20 and 30 ng/mL tacrolimus.	
Similarities	
Both devices are calibrators intended for use as a reference in measuring tacrolimus with their respective assays.	
Both devices contain tacrolimus in preserved whole blood hemolysate.	
Both devices contain 6 levels of calibrators.	
Differences	
The Emit® 2000 Tacrolimus Calibrators consist of 6 calibrator materials with concentrations of – 0, 2.5, 5, 10, 20 and 30 ng/mL while the Abbott IMx® Tacrolimus II Calibrators consist of 6 calibrator materials with concentrations of – 0, 3, 6, 12, 20, and 30 ng/mL.	

K. Standard/Guidance Document Referenced (if applicable):

GUIDANCE			
Document Title	Office	Division	Web Page
Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus	OIVD	DCTD	http://www.fda.gov/cdrh/ode/guidance/1380.html

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

N/A

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The tacrolimus frozen liquid stock solution was prepared gravimetrically from commercially available pharmaceutical grade tacrolimus. Calibrators are prepared by directly spiking the stock solution into whole blood hemolysate to form the target concentrations. Verification occurred via recovery against a master lot. The master lot is formulated by diluting the stock into the whole blood hemolysate with the preservatives at six different levels and stored at 20°C. The potential master lot of calibrators is assigned by multiple runs using the Emit Tacrolimus Assay calibrated with the existing master lot of calibrators verified by LC/MS.

Shelf-life and open vial stability was conducted using real-time data from 3 lots of calibrators. Each level of calibrators was tested in duplicate and replicates of 6 with commercially available control material. The calibrators (stored at -20°C) were tested at 0,1,2,3,7,9,13,15,22,25,31 and 37 months. An open vial stability (stored at 9°C) study was conducted at 0, 8 and 12 weeks. Verification of the 8 week open vial stability throughout the 36 month shelf life, the open vial stability was repeated from 7 to 37 months at 6 month intervals. The study results support the sponsors 8 week open vial and 36 month shelf life stability.

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

N/A

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

c. Other clinical supportive data (when a. and b. are not applicable):

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

The concentrations in the Emit Tacrolimus Calibrators have lot specific values that range from 1 to 30 ng/mL.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

