

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

A. 510(k) Number:

k060503

B. Purpose for Submission:

New device

C. Measurand:

Calibrator for Tacrolimus assay

D. Type of Test:

Not applicable - Calibrator

E. Applicant:

DADE BEHRING, INC.

F. Proprietary and Established Names:

DIMENSION TACR CALIBRATOR

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DLJ	II	21 CFR 862.3200	Toxicology (91)

H. Intended Use:

1. Intended use(s):

The Dimension® TACR Calibrator is an in vitro diagnostic product intended to be used to calibrate the Tacrolimus (TACR) method for the Dimension® clinical chemistry system.

2. Indication(s) for use:

The Dimension® TACR Calibrator is an in vitro diagnostic product intended to be used to calibrate the Tacrolimus (TACR) method for the Dimension® clinical chemistry system.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Dade Dimension clinical chemistry system

I. Device Description:

The Dimension TACR calibrator is a stabilized human whole blood hemolysate product containing tacrolimus. The kit consists of two vials of each calibrator level 1-5. The target concentrations are approximately 0, 3, 6, 12, and 32.5 ng/mL tacrolimus.

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

J. Substantial Equivalence Information:

Predicate		Abbott IMx Tacrolimus II Calibrator P970007
Similarities		
Item	Device	Predicate
Intended use	Calibrators intended for use as a reference in measuring tacrolimus with their respective assays.	Same
Matrix	Whole blood hemolysate	Same
Differences		
Item	Device	Predicate
Target concentrations	0, 3, 6, 12, and 32.5 ng/mL	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 Assays; Guidance for Industry and FDA	OIVD	DCTD	http://www.fda.gov/cdrh/ode/guidance/1380.html

L. Test Principle:

Not applicable - calibrator

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

Purified tacrolimus powder and whole blood hemolysate and are used to prepare a stock solution. The master pool lots are prepared by diluting the stock to obtain specific target concentrations. The concentrations for the reference lot are assigned by LC/MS/MS. The target concentrations are approximately 0, 3, 6, 12, and 32.5 ng/mL tacrolimus.

Shelf-life and opened vial stability studies were conducted using real time data collected from three (3) lots of the TACR cartridge. The data from the sponsor's studies supported a shelf life of 12 months when the product is stored frozen (-15 to -25°C) and opened vial stability of 30 days when the product is stored at 2-8°C.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

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

O. Conclusion:

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