

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

A. 510(k) Number:

K032574

B. Analyte:

Calibrators for the measurement of Acetaminophen, Carbamazepine, Digitoxin, Gentamicin, N-acetylprocainamide, Procainamide, Tobramycin, Valproic Acid, and Vancomycin.

C. Type of Test:

N/A (calibrators only)

D. Applicant:

Dade Behring, Inc.

E. Proprietary and Established Names:

Dade Behring Dimension® Drug Calibrator II

F. Regulatory Information:

1. Regulation section:

CFR 862.3200

2. Classification:

Class II

3. Product Code:

DKB

4. Panel:

Clinical Toxicology

G. Intended Use:

1. Indication(s) for use:

The Dade Behring Dimension® Drug Calibrator II is a device intended for medical purposes for use on the Dade Behring Dimension® clinical chemistry system to establish points of reference that are used in determination of values in the measurement of substances in human specimens. The product is intended for the calibration of the following methods packaged in Dimension® Flex® reagent cartridges:

Acetaminophen (ACTM)

Carbamazepine (CRBM)

Digitoxin (DGTX)

Gentamicin (GENT)

N-acetylprocainamide (NAPA)

Procainamide (PROC)

Tobramycin (TOBR)

Valproic Acid (VALP)

Vancomycin (VANC)

2. Special condition for use statement(s):
Prescription Use Only
3. Special instrument Requirements:
Dade Behring Dimension® Clinical Chemistry System

H. Device Description:

Dade Behring Dimension® Drug Calibrator II is a 5 level multi-drug calibrator for Acetaminophen, Carbamazepine, Digitoxin, Gentamicin, N-acetylprocainamide, Procainamide, Tobramycin, Valproic Acid, and Vancomycin. It is packaged as ten vials (5.0 mL each), two vials at each of five levels.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Dimension® Drug Calibrator II
2. Predicate K number(s):
K990255
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Analytes Included	For the calibration of: Acetaminophen, Carbamazepine, Digitoxin, Gentamicin, N- acetylprocainamide, Procainamide, Tobramycin, Valproic Acid, and Vancomycin	Same as device minus Procainamide and N- acetylprocainamide
Matrix	Bovine serum base	Same
Form	Liquid, ready-to-use	Same
Packaging	Ten vials: two vials at five levels (5.0 mL each)	Same
Value Assignment	USP standards or highest- order purity material available used for anchor lot – commercial product compared to anchor lot	Same

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

None referenced

K. Test Principle:

N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
N/A
 - b. *Linearity/assay reportable range:*
N/A

- c. Traceability (controls, calibrators, or method):*
In – house reference (anchor) lot. Each analyte is traceable to USP drug standard or highest order purity available.
 - 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):*
- 4. Clinical cut-off:
N/A
- 5. Expected values/Reference range:
N/A

M. Conclusion:

Based upon the information provided for the file, I recommend that the Dade Behring Dimension® Drug Calibrator II is substantially equivalent to the predicate device.

