

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

**A. 510(k) Number:**

k062182

**B. Purpose for Submission:**

New device

**C. Measurand:**

Methylenedioxymethamphetamine

**D. Type of Test:**

Calibrator Materials

**E. Applicant:**

Dade Behring, Inc.

**F. Proprietary and Established Names:**

Dimension Vista System Ecstasy Calibrator (EXTC CAL - KC520)

**G. Regulatory Information:**

Product Code	Classification	Regulation Section	Panel
Calibrators, Drug Specific (DLJ)	Class II	21 CFR 862.3200, Clinical toxicology calibrator.	91 Clinical toxicology (TX)

**H. Intended Use:**

1. Intended use(s):

Refer to indications for use below.

2. Indication(s) for use:

The EXTC CAL is an in vitro diagnostic product for the calibration Ecstasy (EXTC) method on the Dimension Vista™ System.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Dade Behring Dimension Vista™ System

**I. Device Description:**

The EXTC CAL is a liquid, multi-analyte, drug free human urine based calibrator consisting of 6 vials (three of calibrator A and three of calibrator B). Calibrator A vials and Calibrator B vials contain 2.3 mL. The component, constituent, and assigned values are listed in the table below. Intermediate levels are prepared and corresponding values calculated by the instrument.

Component	Source	Level A (ng/mL)	Level B (ng/mL)
Methylenedioxymethamphetamine	Methylenedioxymethamphetamine	0	1000

**J. Substantial Equivalence Information:**

The predicate for the EXTC CAL is the Syva EMIT II Plus Ecstasy calibrators/controls (k043028). The EXTC CAL has the same intended use, analytes, form, matrix and traceability. The only noted difference is that the EXTC CAL has two levels whereas the predicate has four levels.

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

**STANDARDS**

**Title and Reference Number**

- 1) CEN 13540 Stability testing of In-Vitro Diagnostic Devices
- 2) ISO 14971: 2000 Medical devices-Application of risk management to medical devices.

**Other Standards**

**GUIDANCE**

Document Title	Office	Division	Web Page
Abbreviated 510k Submissions for In Vitro Diagnostic Calibrators	OIVD	----	<a href="http://www.fda.gov/cdrh/ode/calibrator.html">http://www.fda.gov/cdrh/ode/calibrator.html</a>
Guidance for Industry and FDA Staff; Use of Symbols on Labels and in Labeling of	CDRH CBER		<a href="http://www.fda.gov/cdrh/ocd/guidance/4444.html">http://www.fda.gov/cdrh/ocd/guidance/4444.html</a>

**L. Test Principle:**

Not applicable (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):*

Traceability

The methylenedioxymethamphetamine reference material (99% purity) for the EXTC CAL are traceable to a commercially available provider.

Stability

The sponsor conducted real-time stability studies with the multi-drug calibrator. When punctured (open vial) by the instrument, the vial is stable on board for 24 hours. A non-punctured (open) vial is stable in the refrigerator for 31 days. The closed stability for the EXTC CAL is 12 months.

Value assignment

The new calibrator master lot is made by gravimetrically adding quantities of the reference material into drug free normal human urine. The master lot (5 levels) are stored at -70°C and verified by recovery and GC/MS testing. The commercial lot stock solution is prepared by gravimetrically adding the analytes to form the target concentration. The commercial stock solution concentration is verified by comparing the master lot assigned values. The commercial lot is prepared by adding calculated quantities of the commercial stock solution to drug free normal human urine to the two level target concentrations. The concentration of the commercial lot is verified to be within acceptable ranges using an instrument calibrated with the master lot

and GC/MS testing.

*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:

N/A

**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.