

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

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

k042549

**B. Purpose For Submission:**

Premarket Notification 510(k) of intention to manufacture and market the Wako Chemicals USA, Inc. Multi-Chem Calibrator B

**C. Analyte:**

Glucose, Uric Acid, Urea Nitrogen

**D. Type of Test:** Not Applicable

**E. Applicant:**

Wako Chemicals USA, Inc.

**F. Proprietary and Established Names:**

Multi-Chem Calibrator B

**G. Regulatory Information:**

Regulation section:

1. Regulation section: §862.1150, Calibrator

2. Classification: Class II

3. Product Code: JIX

4. Panel: 75 (Chemistry)

**H. Intended use(s):**

1. Intended use(s):

The Multi-Chem Calibrator B is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Glucose, Uric Acid, and Urea Nitrogen in human serum.

2. Indication(s) for use:

The Multi-Chem Calibrator B is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Glucose, Uric Acid, and Urea Nitrogen in human serum.

3. Special condition for use statement(s): For Prescription Use.4. Special instrument Requirements: Not Applicable**I. Device Description:**

The Multi-Chem Calibrator B is liquid and ready to use. The calibrator consists of 4 x 5 mL bottles of aqueous solutions containing Glucose, Uric Acid, Urea Nitrogen and Sodium Azide. Calibrator traceability has been reference to NIST primary standards with assigned values verified by recognized enzymatic methods. This solution is stable until the date printed on the label when stored as directed.

**J. Substantial Equivalence Information:**1. Predicate device name(s): Wako Glucose, Uric Acid and Urea Standard2. Predicate K number(s): k871758, k871768, k8717673. Comparison with Predicate:

|              | Multi-Chem Calibrator B  | Glucose              | Uric Acid             | Urea Nitrogen             |
|--------------|--|----------------------|-----------------------|---------------------------|
| Format       | Liquid   | Liquid               | Liquid                | Liquid                    |
| Constituents | Glucose<br>300 mg/dL<br><br>Uric Acid<br>10 mg/dL<br><br>Urea Nitrogen<br>30 mg/dL | Glucose<br>300 mg/dL | Uric Acid<br>10 mg/dL | Urea Nitrogen<br>30 mg/dL |
| Storage      | 2-10° C  | 2-10° C              | 2-10° C               | 2-10° C                   |
| 510(K) #     | K042549  | K871758              | K871768               | K871767                   |

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

The Waco Multi-Chem Calibrator B is traceable to NIST referenced standards:

NIST, SRM917b

NIST, SRM913a

NIST, SRM912a

**L. Test Principle:**

Not Applicable

**M. Performance Characteristics (if/when applicable):**1. Analytical performance:

a. *Precision/Reproducibility: Not Applicable*

b. *Linearity/assay reportable range: Not Applicable*

c. *Traceability (controls, calibrators, or method):*

The Waco Multi-Chem Calibrator B is traceable to NIST referenced standards

**Primary Standard**

| Item          | Primary Standard |
|---------------|------------------|
| Glucose       | NIST SRM917b     |
| Uric Acid     | NIST SRM913a     |
| Urea Nitrogen | NIST SRM912a     |

**Multi Chem Calibrator B**

| Item          | Assigned Value | Method                      |
|---------------|----------------|-----------------------------|
| Glucose       | 300 mg/dL      | Assayed by enzymatic method |
| Uric Acid     | 30 mg/dL       | Assayed by enzymatic method |
| Urea Nitrogen | 10 mg/dL       | Assayed by enzymatic method |

The stability of the product was tested over time and the results were compared to the start point of time 0. Percent recoveries were calculated. No recoveries exceeded  $\pm 2.5$  % from time 0. The product is stable at 2-10° C until the date printed on the label.

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:*

The Multi-Chem Calibrator B is designed to be used with Wako's assays to determine the points of reference that are used in the determination of Glucose, Uric Acid and Urea Nitrogen in human serum.

The safety and effectiveness of the Multi-Chem Calibrator B is demonstrated by its substantial equivalency to Wako Glucose, Uric Acid and Urea Nitrogen Standard. The calibration materials are used to calibrate instruments to determine the points of reference. The following are results of the comparison studies against the predicates:

**Glucose (L-Type Glucose 2)**

|  |                         |         |
|--|-------------------------|---------|
|  | n                       | 80      |
|  | Correlation coefficient | 0.9999  |
|  | Slope                   | 1.0015  |
|  | Intercept               | -0.0592 |
|  |                         |         |

**Uric Acid (L-Type UA F reagent)**

|  |                         |         |
|--|-------------------------|---------|
|  | n                       | 70      |
|  | Correlation coefficient | 0.9998  |
|  | Slope                   | 0.9953  |
|  | Intercept               | -0.0096 |
|  |                         |         |

**Urea Nitrogen (L-Type UN reagent)**

|  |                         |        |
|--|-------------------------|--------|
|  | n                       | 70     |
|  | Correlation coefficient | 0.9999 |
|  | Slope                   | 0.9961 |
|  | Intercept               | 0.0743 |
|  |                         |        |

3. Clinical studies:

*a. Clinical sensitivity:*

Clinical studies are not typically submitted for this device type.

*b. Clinical specificity:*

Clinical studies are not typically submitted for this device type.

*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:**Multi Chem Calibrator B**

| Item          | Assigned Value | Method                      |
|---------------|----------------|-----------------------------|
| Glucose       | 300 mg/dL      | Assayed by enzymatic method |
| Uric Acid     | 30 mg/dL       | Assayed by enzymatic method |
| Urea Nitrogen | 10 mg/dL       | Assayed by enzymatic method |

**N. Conclusion:**

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