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

A. 510(k) Number:

k042550

B. Purpose For Submission:

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

C. Analyte:

Cholesterol, HDL, LDL, Triglyceride

D. Type of Test: Not Applicable

E. Applicant: Wako Chemicals USA, Inc.

F. Proprietary and Established Names:

Multi-Lipid Calibrator

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-Lipid Calibrator is designed to be used with Wako's assays to determine the points of reference that are used in the determination of HDL-C, LDL-C, Cholesterol, and Triglycerides in human serum.

2. Indication(s) for use:

The Multi-Lipid Calibrator is designed to be used with Wako's assays to determine the points of reference that are used in the determination of HDL-C, LDL-C, Cholesterol, and Triglycerides in human serum.

3. Special condition for use statement(s):   For Prescription Use.

4. Special instrument Requirements: Not Applicable

I. Device Description:

The Multi-Lipid Calibrator consists of 4 x 5 mL bottles of lyophilized material containing Human HDL-C concentrate, Human LDL-C concentrate, Triolein, and Cholesterol in human serum. Primary calibrator traceability has been reference to the following: T.Cho: HECTEF (Health Care Technology. Foundation) (P-CHO), HDL-C: CDC Reference Method, LDL-C: CDC Reference Method, TG: Glycerol (Assay method: Gas Chromatograph). 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's Cholesterol 20R/30R Standard, HDL/LDL Combo Calibrator, Triglyceride Standard Solution A

2. Predicate K number(s):   k912024, k001005, k871766

3. Comparison with Predicate:

	Multi-Lipid Calibrator	Cholesterol 20R/30R Standard	HDL/LDL-C Calibrator	Triglyceride Standard Non-blanking method 300 mg/dL/200 mg/dL	Triglyceride Standard Blanking method 300 mg/dL/ 200 mg/dL
Format	Lyophilized	Liquid	Lyophilized	Liquid	Liquid
Constituents	Human HDL-C Concentrate Human LDL-C Concentrate Triolein 3.39 mmol/L Human Serum	Cholesterol 5.2 mmol/L	Human HDL-C Concentrate Human LDL-C Concentrate	Triolein 3.39 mmol/L	Triolein 3.39 mmol/L
Storage	2-10 °C	2-10 °C	2-10 °C	2-10 °C	2-10 °C
510(K) #	k042550	k912024/A	k001005	k871766	K010334

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

The Waco Multi-Lipid Calibrator is traceable to the following referenced
standard: Primary Standard
Total Cholesterol   HECTEF (Health Care Technology Foundation) (P-CHO)
HDL-C: CDC Reference Method
LDL-C: CDC Reference Method
TG: Glycerol (Assay method: Gas Chromatograph)

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-Lipid Calibrator is traceable to the following referenced standards:

Primary Standard

Item	Primary Standard or Method
Total Cholesterol	HECTEF (Health Care Technology. Foundation) (P-CHO)
HDL-C:	CDC Reference Method
LDL-C:	CDC Reference Method
TG:	Glycerol (Assay method: Gas Chromatograph).

Secondary Standard
(Working Standard)

Item	Method
Total Cholesterol	Assayed by enzymatic method
HDL-C	Assayed by immunoinhibition method
LDL-C	Assayed by enzyme selective protection method
TG	Assayed by enzymatic method (glycerol blanking method)
	Assayed by enzymatic method (non-blanking method)

Multi Lipid Calibrator

Item	Assigned Value	Method
Cholesterol	200 mg/dL	Assayed by enzymatic method
HDL-C	53 mg/dL	Assayed by immuno inhibition method
LDL-C	127 mg/dL	Assayed by enzyme selective protection method
Triglyceride	300 mg/dL	Assayed by enzymatic method (glycerol blanking method)
		Assayed by enzymatic method (non-blanking method)

Determination: Based on the US CDC reference methods.

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 ± 2.5 % from time 0. The product is stable until the date printed on the label when stored at 2-10º 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:*

The Multi-Lipid Calibrator is designed to be used with Wako's assays to determine the points of reference that are used in the determination of HDL-C, LDL-C, Cholesterol, and Triglycerides in human serum. The safety and effectiveness of the Multi-Chem Calibrator B is demonstrated by its substantial equivalency to Wako's Cholesterol 20R/30R Standard, HDL/LDL Combo Calibrator, Triglyceride Standard Solution A.

 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:

Cholesterol (L-Type Cholesterol H reagent)

	N	60
	Correlation coefficient	0.9996
	Slope	1.0236
	Intercept	0.6192

HDL-C (L-Type HDL-C reagent)

	N	60
	Correlation coefficient	0.9995
	Slope	0.9959
	Intercept	0.2445

LDL-C (L-Type LDL-C reagent)

	n	60
	Correlation coefficient	0.9996
	Slope	0.9923
	Intercept	0.6913

Triglyceride (L-Type Triglyceride reagent)

	N	60
	Correlation coefficient	1.000
	Slope	1.0125
	Intercept	0.0936

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 Lipid Calibrator

Item	Assigned Value	Method
Cholesterol	200 mg/dL	Assayed by enzymatic method
HDL-C	53 mg/dL	Assayed by immunoinhibition method
LDL-C	127 mg/dL	Assayed by enzyme selective protection method
Triglyceride	300 mg/dL	Assayed by enzymatic method (glycerol blanking method)
		Assayed by enzymatic method (non-blanking method)

Determination: Based on the US CDC reference methods.

N. Conclusion:

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