

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

A. 510(k) Number: K040918

B. Purpose for Submission: Notification of intent to manufacture and market the device: Lipid Control

C. Analyte: Lipids – Triglyceride, HDL-Cholesterol, LDL-Cholesterol, Total Cholesterol, Phospholipids, Apolipoproteins, NEFA C, Free Cholesterol and beta Lipoprotein.

D. Type of Test: n/a

E. Applicant: Wako Chemicals USA, Inc

F. Proprietary and Established Names: Wako Lipid Control – Quality Control Material

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1660
2. Classification: Class I
3. Product Code: JJX
4. Panel: 75

H. Intended Use:

1. Intended use(s): The Wako Quality control is intended for use as an assay quality control serum to monitor the precision of laboratory testing procedures for the Wako Lipid assays such as Triglyceride, HDL-Cholesterol, LDL-Cholesterol, Total Cholesterol, Phospholipids, Apolipoproteins, NEFA C, Free Cholesterol and beta Lipoprotein.
2. Indication(s) for use: The Wako Quality control is intended for use as an assay quality control serum to monitor the precision of laboratory testing procedures for the Wako Lipid assays such as Triglyceride, HDL-Cholesterol, LDL-Cholesterol, Total Cholesterol, Phospholipids, Apolipoproteins, NEFA C, Free Cholesterol and beta Lipoprotein.
3. Special condition for use statement(s): none
4. Special instrument Requirements: none

I. Device Description: Quality Control Material (Assayed and unassayed)

J. Substantial Equivalence Information:

1. Predicate device name(s): Wako Prealbumin Control
2. Predicate K number(s): k040226
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Control for human lipid assays	Control for human prealbumin
Differences		
Item	Device	Predicate
Form	Liquid	Liquid
Levels	2 levels	2 levels
Vial volume	5ml	5ml
Matrix	Human	Human
Storage	2-8 °C	2-10 °C

K. Standard/Guidance Document Referenced (if applicable): No standard or guidance was listed

L. Test Principle: 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 (controls, calibrators, or method)*: None provided
 - 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: NA

b. Matrix comparison: NA

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. Conclusion:

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