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

A. 510(k) Number:
k032285

B. Analyte:
Prealbumin

C. Type of Test:
Immunoturbidometric

D. Applicant:
Olympus America Inc.

E. Proprietary and Established Names:
Olympus Prealbumin Calibrator

F. Regulatory Information:
1. Regulation section:
   21CFR 862.1150 Calibrator
2. Classification:
   Class II
3. Product Code:
   JIT
4. Panel:
   Clinical Chemistry

G. Intended Use:
1. Indication(s) for use:
   The Olympus Prealbumin Calibrator is a device designed to provide suitable calibration levels for OLYMPUS analyzers employing the OLYMPUS Prealbumin immunoturbidometric assay for Prealbumin determinations in human serum.
2. Special condition for use statement(s):
   Prescription Use Only
3. Special instrument Requirements:
   OLYMPUS analyzers employing the immunoturbidometric assay for Prealbumin

H. Device Description:
The Olympus Prealbumin Calibrator consists of 5 bottles (2 mL each) labeled 1-5 with increasing concentrations of human prealbumin in a human serum matrix.

I. Substantial Equivalence Information:
1. Predicate device name(s):
   Dade Behring Dimension Prealbumin Calibrator
2. Predicate K number(s):
   k982292

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Calibration for human prealbumin	Calibration for human prealbumin
Form	Liquid	Liquid
Differences		
Item	**Device**	**Predicate**
Matrix Base	Human Serum	Bovine Albumin
Vial volume	2 mL	1 mL
Levels	5	4 plus a Zero Calibrator

J. Standard/Guidance Document Referenced (if applicable):
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

K. Test Principle:
Immunoturbidometric

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):*
   Traceable to IFCC CRM 470
   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. <u>Expected values/Reference range:</u>
   N/A

M. Conclusion:

Based upon the information provided for the file, I recommend that the Olympus Prealbumin calibrator is substantially equivalent to the predicate device.