

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

A. 510(k) Number:

K033344

B. Analyte:

Quality control material (assayed and unassayed)

C. Type of Test:

Quantitative

D. Applicant:

Consolidated Technologies, Inc.

E. Proprietary and Established Names:

Ligand Plus Control

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1660
2. Classification:
Quality control material (assayed and unassayed)
3. Product Code:
JJY
4. Panel:
75

G. Intended Use:

1. Intended use(s):
Ligand Plus Control is a lyophilized, human serum based assayed quality control material intended to monitor the performance of clinical immunochemistry and therapeutic drug test procedures.
2. Indication(s) for use:
Ligand Plus Control, Levels 1, 2 and 3, is a lyophilized human serum based assayed quality control material intended to monitor the performance of clinical immunoassay test procedures that analyze immunochemistries and therapeutic drugs as listed in this package insert.
3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
See the assay sheet provided

H. Device Description:

The device contains purified human and animal components, purified drugs and non-organic components added to a human serum based matrix, for a total of 55 analytes. The control is supplied lyophilized in five- 5.0 mL vials at three levels.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Immunoassay Plus Control
2. Predicate K number(s):
K020237
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Assayed or unassayed quality control for monitoring performance of routine chemistry test procedures	Assayed or unassayed quality control for monitoring performance of routine chemistry test procedures
Matrix	Processed human serum	Processed human serum
Form	Lyophilized	Lyophilized
Levels	3 Levels	3 Levels
Differences		
Item	Device	Predicate
Analytes of clinical significance	55 analytes	59 analytes

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

None Referenced

K. Test Principle:

Not applicable

L. 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):*
Purified human and animal components

- 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:*
Not applicable
 - b. Matrix comparison:*
Not applicable
- 3. Clinical studies:
 - a. Clinical sensitivity:*
Not applicable
 - b. Clinical specificity:*
Not applicable
 - 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:

The assay values and expected ranges are target values derived from interlaboratory data. The expected range values include variations of instrument, reagent and laboratory handling. The assay values were obtained using in-date reagents available at the time of testing. Overall group mean and standard deviation per constituent per method was calculated.

M. Conclusion:

The Ligand Plus Control is similar to the predicate device in intended use, matrix, form, constituents, and stability. In addition, the manufacturing, stability, and value assignment information provided for the control were adequate. I recommend a substantial equivalence determination for the Ligand Plus Control.