

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

A. 510(k) Number:

k071039

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator for Na⁺, K⁺ and Cl⁻ for the Olympus AU400 and AU600 instruments.

D. Type of Test:

Calibration

E. Applicant:

Diamond Diagnostics Inc.

F. Proprietary and Established Names:

Mission Olympus AU ISE Calibrators

G. Regulatory Information:

1. Regulation section:
21 CFR § 862. 1150, Calibrator
2. Classification:
Class II
3. Product Code:
JIT
4. Panel:
Chemistry (75)

H. Intended Use:

1. Intended use(s):

Mission Olympus AU ISE Calibrators are intended to provide calibration points for Na⁺, K⁺ and Cl⁻ electrodes on the Olympus AU400 and AU600 instruments.

2. Indication(s) for use:

See Intended use(s)

3. Special conditions for use statement(s):

Prescription Use Only

4. Special instrument requirements:

Olympus AU400 and AU600

I. Device Description:

Mission Olympus AU ISE Calibrators are aqueous solution of salts and preservatives.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Olympus AU ISE Calibrators

2. Predicate K number(s):

k981743 and k961274

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Contents	Aqueous solution of salts & preservatives, Contains no human or animal materials	Aqueous solution of salts & preservatives, Contains no human or animal materials
Intended Use	For in-vitro diagnostics use to provide calibration for Na ⁺ , K ⁺ and Cl ⁻ electrodes	For in-vitro diagnostics use to provide calibration for Na ⁺ , K ⁺ and Cl ⁻ electrodes

Similarities		
Item	Device	Predicate
	on the Olympus AU400 and AU600 instruments	on the Olympus AU400 and AU600 instruments
Storage	18 to 25 ⁰ C	18 to 25 ⁰ C

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

Not applicable

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, Stability, Expected values (controls, calibrators, or methods):*

Reference is made to either an aqueous standard made with corresponding analyte NIST material or the Original Equipment Manufacturers (OEM) Calibrator. The calibrators' shelf-life stability are verified to be 24 months stored at room temperature.

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:
Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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