

**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.