

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

A. 510(k) Number:

k120591

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator materials for serum and urine Potassium, Chloride, Sodium

D. Type of Test:

Calibrator materials

E. Applicant:

Diamond Diagnostics Inc

F. Proprietary and Established Names:

Diamond Calibrators for Tokyo Boeki ISE Module

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
JIT	<u>Class II</u>	<u>21 CFR 862.1150</u>	Calibrator

2. Classification:

Class II

3. Product Code:

JIT

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

Refer to Indications for use below.

2. Indication(s) for use:

Diamond calibrator for Tokyo Boeki ISE Module are intended for in vitro diagnostics use to provide calibration points for the Na⁺, K⁺, and Cl⁻ electrodes on the Tokyo Boeki Prestige 24i, Biolis 24i, MGC 240 and SIRRUS instruments in both Human Serum and Human Urine modes.

3. Special condition for use statement(s):

Prescription use

4. Special instrument Requirements:
Tokyo Boeki Prestige 24i, Biolis 24i, MGC 240 and Sirrus instruments

I. Device Description:

Diamond Calibrators consist of a buffered solution of electrolytes and preservative. The matrix of Diamond Calibrators is deionized water added with chemicals and a resistivity of at least 10 mega-ohms. No human or animal products are used in the calibrators.

Each calibrator is comprised of the following concentrations of analytes,

PN	ISE Module Calibrator	Na	K	Cl
		mmol/L	mmol/L	mmol/L
TB-202704770	Calibrator 1	140 ± 2.0	4.00 ± 0.05	100 ± 2
TB-202704780	Calibrator 2	160 ± 2.0	6.0 ± 0.05	120 ± 2

PN	ISE Module Calibrator	Na	K	Cl
		mmol/L	mmol/L	mmol/L
TB-20270480AD	Urine Calibrator 1	10 ± 0.5	1.50 ± 0.03	12 ± 0.5
TB-2027048080	Urine Calibrator 2	60 ± 1.0	25.0 ± 1.0	85 ± 2

J. Substantial Equivalence Information:

1. Predicate device name(s):
Tokyo Boeki ISE Module Calibrators
2. Predicate K number(s):
k040958
3. Comparison with predicate:

Calibrator values are the same for the new device and predicate (Table 1).

Characteristics	Diamond Calibrators for Tokyo Boeki ISE Module Calibrators (New Device)	Tokyo Boeki ISE Module Calibrators (Predicate Device, K040958)
Similarities		
Intended Use	This device are intended for in-vitro diagnostics use to provide calibration points for sodium, potassium, and chloride electrodes on the Tokyo Boeki Prestige 24, Biolis 24, MGC 240, Sapphire 400, Sirius, TMS-1024, TRX-7010, and Labmax 240 instruments in both human serum and human urine modes.	Same as new device.
Matrix	Buffered solution of salts & preservatives contains NO human or animal materials	Same as new device.
Analytes	Potassium, Chloride, Sodium	Same as new device.
Storage	18 °C to 25 °C	Same as new device.
Shelf life of product	24 months	Same as new device.

Differences		
510 (K)	K120591	K040958
PN	TB-20270477D, TB-20270478D, TB-20270480D	20-27-0477, 20-27-0478, 20-27-0480

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

None were referenced

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 (controls, calibrators, or method):*

a). Traceability

Six replicates of each sample are tested analytically for the electrolytes using reference methods. Flame Photometry is used for the Na⁺ and K⁺. Titration method is used for the Cl⁻. The IL 943 Flame Photometer is used for testing the Na⁺ and K⁺, and the Corning 925 instrument is used for testing the Cl⁻.

The exception is the Urine Calibrator 2, where the chloride is tested on the SAT-500 Analyzer due to a low chloride concentration, 12mmol/L. Lot to lot variation is determined by analytically testing new lot vs. previous lot and predicate device, then normalized to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or a known Calibrator based on reference methods (shown below).

Analyte	Standard Used for Determination of Analyte Value	Instrument Used
Na, K, Cl	NIST 919a, 918a NIST 919a	IL 943 (Flame Photometry) Corning 925, SAT-500 Salt Analyzer (Titrimetric)

b.) Value Assignment (Controls, Calibrators, or Methods)

Assigned values for Na⁺, K⁺, Cl⁻ were obtained from six replicates in Tokyo Beoki ISE module using NIST standard materials.

c.) Stability

Stability was determined using an accelerated (high temperature) stress test. The results from the accelerated stress tests support 2 years shelf life when stored at 18-25°C. Real time studies are being performed. Storage temperature of the devices is 18-25°C. Results of stability tests for the open and closed vial are provided. Opened vials showed Na⁺, K⁺, and Cl⁻ remained within specification after 60 days.

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 available.

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 substantial equivalence decision.