

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

A. 510(k) Number:

k093357

B. Purpose for Submission:

New device

C. Measurand:

Calibrator material for Na⁺, K⁺, and Cl⁻

D. Type of Test:

Not applicable

E. Applicant:

Diamond Diagnostics

F. Proprietary and Established Names:

Diamond Calibrators for Medica ISE Modules

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIT	Class II	21 CFR 862.1150	Chemistry 75

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Diamond Calibrators for Medica ISE Modules are intended for *in-vitro* diagnostics use to provide calibration points for the Na⁺, K⁺, and Cl⁻ electrodes on the Polymeco Poly-Chem, and Randox Daytona instruments having the Medica ISE Module.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

Poly-Chem analyzer and Randox Daytona analyzer with Medica ISE Module

I. Device Description:

Calibrant A consists of a buffered solution which contains 140 mmol/L Na⁺, 4 mmol/L K⁺, 125 mmol/L Cl⁻ and preservatives. It is packaged in a foil bag with a draw tube and covered in a corrugated box. Each foil bag contains 500 mL of solution. This device contains no human or biological materials.

Calibrant B consists of a buffered solution which contains 70 mmol/L Na⁺, 8 mmol/L K⁺, 41 mmol/L Cl⁻ and preservatives. It is packaged in a brown plastic bottle with a cap. Each plastic bottle contains 125 mL of solution. This device contains no human or biological materials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Medica ISE Module Calibrator

2. Predicate 510(k) number(s)

k070057

3. Comparison with predicate:

Similarities		
Item	Candidate Device Diamond Calibrators for Medica ISE Module	Predicate Device Medica ISE Module Calibrators (k070057)
Indications for Use	For <i>in-vitro</i> diagnostic use to provide calibration points for Na ⁺ , K ⁺ , and Cl ⁻ electrodes on the instruments having the Medica ISE Module	Same
Matrix	Buffered solution of salts and preservatives. Contains NO human or animal materials.	Same
Packaging	Calibrant A is contained within a foil bag. Calibrant B is contained within a dark brown plastic bottle.	Same
Storage	18-25°C	Same

Differences		
Item	Device	Predicate
Shelf Life	<p>Calibrant A – Shelf life is 30 months, open vial stability is 30 days;</p> <p>Calibrant B – Shelf life is 28 months, open vial stability is 1 hour after pipetting into sample cup.</p>	36 months

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

Abbreviated 510(k) Submissions for In Vitro Calibrators; Final Guidance for Industry- February 1999

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):

Traceability

Sponsor claims traceability to the following material:

Analyte	Standard Used for Determination of Analyte Value
Na, K,	NIST 919a, 918a
Cl	NIST 919a

Value Assignment

Commercially available salts/chemical constituents are gravimetrically weighed and added to Type 1 deionized water to yield the desired concentrations. To ensure that target values are met, multiple replicates of test samples are measured at the beginning and end of the production run on multiple analyzers. Values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot. Samples are then tested against previous lots normalized to either an aqueous standard made with corresponding analyte NIST (National Institute of Standards and Technology) material or a known calibrator.

Stability

Accelerated stability testing protocols and acceptance criteria were described and found to be adequate. Calibrant A has an estimated shelf life of 30 months when stored at 18-25°C. Calibrant B has an estimated shelf life of 28 months when stored in the dark at 18-25°C. On Board stability for Calibrant A is 30 days. On-Board stability for Calibrant B, after pipetting into a sample cup, is 1 hour. Real time stability testing is ongoing.

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:

An example of the lot specific target values are as follows:

ISE Module Calibrator	Na ⁺	K ⁺	Cl ⁻
	mmol/L	mmol/L	mmol/L
Calibrator A	140 ± 2.0	4.00 ± 0.05	125 ± 2.0
Calibrator B	70 ± 1.5	8.0 ± 0.08	41 ± 1.5

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.