510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K252488

B Applicant

Radiometer Medicals ApS

C Proprietary and Established Names

ABL90 FLEX PLUS System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CGA	Class II	21 CFR 862.1345 - Glucose Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

Modification to a previously cleared device.

B Measurand:

Glucose (cGlu)

C Type of Test:

Amperometry: Glucose

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures:

-glucose in heparinized capillary whole blood.

The ABL90 FLEX PLUS System is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient, or point-of-care setting.

These tests are only performed under a physician's order.

Glucose (cGlu): Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

D Special Instrument Requirements:

ABL90 FLEX PLUS System

IV Device/System Characteristics:

A Device Description:

The ABL90 FLEX PLUS System consists of the ABL90 FLEX PLUS analyzer, sensor cassette (SC) and solution pack (SP) consumables, and related accessories for the analyzer as described in K240998. The ABL90 FLEX PLUS System has an automated sample inlet mechanism, which can collect arterial and venous whole blood through two different measuring modes: the S65 syringe mode and the SP65 short probe mode, and capillary whole blood through the C65 capillary mode.

For the C65 modes, samples are loaded using safeCLINITUBES which are 70 and 100µL plastic capillary tubes with balanced heparin, mixing wires and end caps.

This submission is for the addition of capillary heparinized whole blood samples for cGlu.

The ABL90 FLEX PLUS System is cleared for the quantitative measurement of pH, pO2, pCO2, oximetry (sO2, ctHb, FO2Hb, FCOHb, FMetHb, FHHb) cK+, cNa+, cCa2+, cCl^-, cGlu, and

cLac using arterial and venous heparinized whole blood samples (K240998, K241037, K252207). The system is cleared for the quantitative measurement of pH, pCO2, ctHb, Cl-, cK+, cNa+, and cCa2+ using capillary heparinized whole blood sample (K240998, K241037, K252207 and K252475).

B Principle of Operation:

Amperometry: The magnitude of an electrical current that flows through an electrode chain is proportional to the concentration of the substance that is oxidized or reduced at an electrode in the chain. The amperometric measuring principle is applied in the cGlu sensor.

V Substantial Equivalence Information:

A Predicate Device Name(s):
i-STAT G cartridge with the i-STAT 1 System

B Predicate 510(k) Number(s):
K223755

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252488	K223755
Device Trade Name	ABL90 FLEX PLUS System	i-STAT G cartridge with the i-STAT 1 System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended to measure glucose in capillary blood samples	Same
Intended Use Environment	Laboratory environment, or point-of-care setting	Same
General Device Characteristic Differences		
Reportable Range	18-738 mg/dL	20-700 mg/dL

VI Standards/Guidance Documents Referenced:

Clinical and Laboratory Standards Institute (CLSI) EP05-A3 – Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

CLSI EP09c 3rd Edition – Measurement Procedure Comparison and Bias Estimation Using Patient Samples

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Within Sample Precision - Capillary Mode Fingerstick
A multi-day precision study to assess heparinized capillary whole blood sample within-run precision in capillary mode was performed at two sites by at least two POC operators at each site. Capillary whole blood from 39 donors via finger stick puncture from two (2) fingers into 2 *safe*CLINITUBE capillary tubes was collected. Blood from each capillary pair was analyzed in singlet in capillary mode on one ABL90 FLEX PLUS analyzer. Samples were grouped into subintervals based on their mean values. The results are summarized below.

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
cGlu (mg/dL)	6	65 - <99	94.483	1.507	1.60
	60	99 - <200	134.82	2.433	1.81
	12	200 - <594	231.33	7.436	3.21

2. Linearity:

Linearity for cGlu was previously established in K241037.

3. Analytical Specificity/Interference:

Interference for cGlu was established in K241037.

4. Assay Reportable Range:

The results from the studies support the claimed reportable range:
cGlu 18-738 mg/dL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability of cGlu is described in K241037.

Sample Stability:

Capillary samples are intended to be used immediately.

6. Detection Limit:

Detection limits for cGlu were established in K241037.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison studies were conducted for *c*Glu using heparinized whole blood capillary samples for testing according to CLSI EP09c.

Capillary blood samples (with fewer than 10% contrived) collected across 2 POC sites in 2 *safe*CLINITUBE capillary tubes, with at least two POC users per site were compared to arterial and venous whole blood specimens tested on a comparator method. Specifically, each capillary whole blood sample was measured once on the candidate device in C65 mode and once on the comparator device. A comparison between the two measurements was performed using linear regression analysis. The regression analyses are summarized below.

Parameter	n	Range Min	Range Max	Intercept	Slope	R^2	MDL	Bias at MDL
cGlu (vs. Arterial on comparator) (mg/dL)	114	37.2 mg/dL	684 mg/dL	-0.724	1.01	1.00	65	0.02
							200	1.57
cGlu (vs. Venous on comparator) (mg/dL)	116	15.5 mg/dL	684 mg/dL	-0.206	1.01	0.97	65	0.17
							200	0.96

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The sponsor included reference range information in the labeling.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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