May 1, 2026

Radiometer Medicals ApS
Andrea Swingle
Senior Specialist, Regulatory Affairs
Åkandevej 21
2700 Brønshøj
Denmark

Re: K252475
Trade/Device Name: ABL90 FLEX PLUS System
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: Class II
Product Code: JGS, JFP, CGZ
Dated: April 2, 2026
Received: April 2, 2026

Dear Andrea Swingle:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

PAULA V. CAPOSINO -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252475

Device Name
ABL90 FLEX PLUS System

Indications for Use *(Describe)*
The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures electrolytes:

- cCl- in heparinized arterial, venous and capillary whole blood, and
- cCa2+ and cNa+ 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.

Calcium (cCa2+): Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Sodium (cNa+): Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Chloride (cCl–): Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K252475

The information provided in this 510(k) summary is in accordance with 21 CFR 807.92.

Submitter Information:

Company Name:	Radiometer Medical ApS
ER Number:	3002807968
Address:	Aakandevej 21 2700 Broenshoej Denmark
Contact Person:	Hsiao-Qing Chow
Phone:	+45 31401578

Application Correspondent:

Name:	Andrea Swingle
Function:	Senior Specialist, Regulatory Affairs
Email:	andrea.swingle@radiometeramerica.com
Phone:	+1 510 246 2559

Date prepared: May 1, 2026

Device Information

Device Trade Name:	ABL90 FLEX PLUS System
Common Name:	Electrolyte test
Regulations:	21 CFR 862.1665, *Sodium test system* 21 CFR 862.1170, *Chloride test system* 21 CFR 862.1145, *Calcium test system*
Product Codes:	**JGS**, CGZ, JFP
Device Class:	Class II

Predicate Device

Device Trade Name:	Stat Profile Prime Plus Analyzer System
Common Name:	Blood Analyzer
510(k) :	K200403
Regulations:	21 CFR 862.1665, *Sodium test system* 21 CFR 862.1170, *Chloride test system* 21 CFR 862.1145, *Calcium test system*
Product Codes:	**JGS**, CGZ, JFP
Device Class:	Class II
Classification Panels:	Clinical Chemistry

Device Description

The ABL90 FLEX PLUS System consists of the ABL90 FLEX PLUS analyzer, sensor cassette and solution pack consumables, and related accessories for the analyzer. The ABL90 FLEX PLUS is a portable, automated system intended for in vitro testing that quantitatively measures:

- $c\mathrm{Cl}^-$ in heparinized capillary, arterial, and venous whole blood, and
- $c\mathrm{Na}^+$ and $c\mathrm{Ca}^{2+}$ in heparinized capillary whole blood.

The ABL90 FLEX PLUS System has an automated sample inlet mechanism, which can collect blood through three different measuring modes: (a) the S65 syringe mode and the SP65 short probe mode for venous and arterial samples and (b) the C65 mode for capillary samples.

Intended Use

The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures electrolytes:

- $c\mathrm{Cl}^-$ in heparinized capillary, arterial and venous whole blood, and
- $c\mathrm{Ca}^{2+}$ and $c\mathrm{Na}^+$ 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.

Calcium ($c\mathrm{Ca}^{2+}$): Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Sodium ($c\mathrm{Na}^+$): Sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Chloride ($c\mathrm{Cl}^-$): Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Substantial Equivalence Comparison

Table 1: Substantial Equivalence Comparison

	Subject device: ABL90 FLEX PLUS System (K252475)	**Predicate device: Stat Profile Prime Plus Analyzer System (K200403)**
Manufacturer	Radiometer Medical ApS	Nova Biomedical Corporation
Intended Use/ Indications for Use	The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures electrolytes: • *c*Cl^- in heparinized arterial, venous and capillary whole blood, and • *c*Na^+ and *c*Ca^{2+} in heparinized capillary whole blood.	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Sodium, Potassium, Chloride, Ionized Calcium, and Ionized Magnesium in heparinized arterial and venous whole blood.
Intended use environment	Laboratory environment, near patient or point-of-care setting	Clinical laboratory and point-of-care settings
Prescription/OTC Use	Prescription	Prescription
Sample requirements		
Sample type	Heparinized whole blood (arterial, venous, capillary)	Heparinized whole blood (arterial, venous)
Sample volume	65 µL	135 µL
Sample preparation	With balanced heparin anticoagulant	With lithium heparin anticoagulant
Device design		
Operating principles	Potentiometry	Potentiometry
Consumables	• Sensor cassette • Solution pack	• Sensor cartridges • Thermal paper
Performance characteristics		
Reportable ranges	*c*Na^+: 116-180 mEq/L	*c*Na^+: 80-200 mmol/L (mEq/L)
	cCl^- : 86-151 mEq/L	*c*Cl^- : 50-200 mmol/L (mEq/L)
	cCa^{2+}: 2-9.94 mg/dL	*c*Ca^{2+}: 0.4-10.8 mg/dL

Analytical Performance Testing Summary

The ABL90 FLEX PLUS System has been tested for analytical performance, including tests for linearity, limit of blank, detection and quantification, precision, bias, interference, and stability. The tests were conducted in general accordance with Clinical Laboratory Standards Institute (CLSI) guidelines, all of which are FDA-recognized consensus standards.

Linearity

Linearity testing was conducted in general accordance with CLSI EP06, *Evaluation of the Linearity of Quantitative Measurement Procedures*, 2nd Edition and EP39, *A Hierarchical*

Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests, 1st Edition. The resulting linearity interval is listed in Table 2.

Table 2: Linearity results

Parameter	Linearity interval
cCl^-	70.1 - 165.0 mEq/L

Detection

Detection capability testing in terms of limit of quantitation (LoQ) was conducted. in general accordance with CLSI EP17-A2, *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures*, and EP39, *A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests*, 1st Edition. Table 3 shows the results of the detection testing.

Table 3: Detection results

Parameter	Unit	LoQ
cCl^-	mmol/L	77

Precision

Five precision studies were performed; all were in general accordance with CLSI EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures*.

Precision using stable, aqueous ampoule-based QC material (three studies)

The primary endpoints of the studies were repeatability and within laboratory precision pooled across several sites. The sample material was either Radiometer QUALICHECK5+ QC ampoules or Radiometer QUALICHECK7+ QC ampoules. Tables 4-6 present the data on the primary and secondary endpoints for each study.

Table 4: Precision results using QUALICHECK5+ ampoules, external sites

Parameter	QC ampoule	N	Mean	Repeatability		Within Lab Precision		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%
***c*Cl^- (mEq/L)**	QC5+ L1	243	123	0.1	0.1	0.7	0.6	0.7	0.6
	QC5+ L2	244	97	0.1	0.1	0.2	0.2	0.2	0.2

N: Number of data points for analysis, SD: Standard Deviation, CV%: %Coefficient of Variation, QC5+ L **X:** QUALICHECK5+ Level **X**

Table 5: Precision results using QUALICHECK7+ ampoules, external sites

Parameter	QC ampoule	N	Mean	Repeatability		Within Lab Precision		Between Laboratory Precision	
				SD	CV%	SD	CV%	SD	CV%
***c*Cl^- (mEq/L)**	QC7+ L1	101	93	0.1	0.1	0.3	0.4	0.4	0.4
	QC7+ L2	102	99	0.1	0.1	0.2	0.2	0.2	0.2
	QC7+ L3	101	140	0.1	0.1	0.3	0.2	0.3	0.2

N: Number of data points for analysis, SD: Standard Deviation, CV%: %Coefficient of Variation, QC7+ L **X:** QUALICHECK7+ Level **X**

Table 6: Precision results using QUALICHECK7+ ampoules, internal site

Parameter	QC ampoule	N	Mean	Repeatability		Within Analyzer Precision		Between Analyzer Precision	
				SD	CV%	SD	CV%	SD	CV%
cCl^- (mEq/L)	QC7+ L1	234	93	0.1	0.1	0.2	0.3	0.2	0.3
	QC7+ L2	234	99	0.1	0.1	0.2	0.2	0.2	0.2
	QC7+ L3	240	140	0.2	0.1	0.4	0.3	0.4	0.3

N: Number of data points for analysis, SD: Standard Deviation, CV%: %Coefficient of Variation, QC7+ L **X:** QUALICHECK7+ Level **X**

Precision using whole blood (two studies)

The scope of the precision study was to estimate the repeatability in (a) S65 and SP65 modes for *c*Cl^- in arterial and venous whole blood (see Table 7) and in (b) C65 mode for *c*Cl^-, *c*Na^+, and *c*Ca^{2+} in capillary whole blood (see Table 8).

Table 7: Precision results using adult arterial and venous whole blood: cCl^- in syringe modes

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
S65 Mode					
cCl^- (mEq/L)	30	80 - <98	95.857	0.154	0.16
	108	98 - 107	103.62	0.124	0.12
	90	>107 - <130	110.46	0.102	0.09
	18	130 - <150	141.59	0.108	0.08
SP65 Mode					
cCl^- (mEq/L)	34	80 - <98	95.612	0.064	0.07
	108	98 - 107	103.62	0.073	0.07
	84	>107 - <130	110.50	0.071	0.06
	18	130 - <150	141.34	0.058	0.04

N: Number of data points for analysis, Test interval: Range of values studied, SD: Standard Deviation, CV%: %Coefficient of Variation

Table 8: Precision results using capillary whole blood: cCl^-, cNa^+ and cCa^{2+} in capillary mode

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
cNa^+ (meq/L)	78	127-151	142	0.8	0.5
cCa^{2+} (mg/dL)	78	4.44-5.82	4.97	0.055	1.1
cCl^- (mEq/L)	78	98-120	108	0.8	0.7

N: Number of data points for analysis, Test interval: Range: Range of values studied, SD: Standard Deviation, CV%: %Coefficient of Variation

Method comparison

Bias was determined by conducting method comparison studies. The comparator device was the ABL90 FLEX PLUS analyzer as it was designed at the time of the clearance of either

K160153 or K241037, in terms of its characteristics related to analytical performance. Two studies were conducted: one method comparison using arterial and venous samples in S65 and SP65 modes for $c\mathrm{Cl}^-$ (see Table 9); and one comparing capillary whole blood samples in C65 mode to arterial and venous whole blood samples in S65 mode for $c\mathrm{Cl}^-$, $c\mathrm{Na}^+$ and $c\mathrm{Ca}^{2+}$ measured on a cleared device (see Table 10).

Table 9: Method comparison results in adult arterial and venous whole blood in S65 and SP65 modes, *cCl⁻*

Parameter	Blood type	Mode	n	Min-max	Intercept	Slope	R^2	MDL 1 MDL 2	Bias at MDL 1 Bias at MDL 2
$c\mathrm{Cl}^-$ (meq/L)	A	S65	222	88-148.1	-0.26	1.00	1.00	98	-0.374
								107	-0.385
		SP65	215	89.2-148.2	0.02	1.00	1.00	98	-0.334
								107	-0.366
	V	S65	231	86.2-148.1	-0.22	1.00	1.00	98	-0.339
								107	-0.350
		SP65	221	86.5-148.2	-0.09	1.00	1.00	98	-0.319
								107	-0.340

N: Number of samples, A: Arterial, V: Venous, Min-max: Range of values measured, MDL: Medical Decision Level/Medical Decision Point

Table 10: Method comparison results comparing capillary samples (in C65 mode) to arterial and venous whole blood samples (in S65 mode), all parameters

Parameter	Comparator Blood Type	n	Min-max	Intercept	Slope	R^2	MDLs	Bias at MDLs
$c\mathrm{Ca}^{2+}$ (mg/dL)	A	111	2.53-9.78	0.442	0.94	0.97	3.41	0.24
							4.60	0.17
							5.17	0.14
							5.81	0.10
	V	111	2.53-9.78	0.338	0.95	0.96	3.41	0.17
							4.60	0.11
							5.17	0.08
							5.81	0.05
$c\mathrm{Na}^+$ (meq/L)	A	116	117-179	-0.542	1.02	0.93	136	2.05
							146	2.24
	V	116	117-179	-0.964	1.02	0.93	136	1.85
							146	2.06
$c\mathrm{Cl}^-$ (meq/L)	A	115	88.4-149	-1.512	1.02	0.96	98	0.54
							107	0.73
	V	116	88.4-149	2.753	1.00	0.96	98	2.39
							107	2.35

N: Number of samples, A: Arterial, V: Venous, Min-max: Range of values measured, MDL: Medical Decision Level/Medical Decision Point

Interference

Interfering substances were evaluated based on testing conducted in general accordance with CLSI, EP07, *Interference Testing in Clinical Chemistry*, 3rd Edition, and CLSI EP37, *Supplemental Tables for Interference Testing in Clinical Chemistry,* 1st Edition. The interference testing consists of two parts: paired-difference and dose-response studies. The paired-difference study was conducted on a large panel of likely interferents, using clinically significant amount of the interferents. Dose-response studies were only conducted in cases where a clinically significant interferent effect was noted during the paired different study. Table 11 and Table 12 summarize the testing that was performed. Specific values for level of interference are included in the *Interference* subsection of Section 10, *Performance Characteristics*, of the IFUs.

Table 11: Interference testing

Interferent	***c*Cl⁻**
Intralipid	-
Hemolysis	-
Bilirubin (unconj)	-
Bilirubin (conj)	-
Biotin	-
Propofol	-
Fluoride (sodium-)	-
Ammoniumchloride (NH_4^+)	-
Ascorbate (sodium-)	-
Benzalkonium chloride	-
Leflunomide	-
Nortriptyline	-
Teriflunomide	-
pH @ low level	X
pH @ high level	-
Perchlorate ClO_4^-	X
Oxalate (sodium-)	-
Salicylic acid	-
Acetylsalicylic acid	-
Citrate (trisodium citrate $2H_2O$)	-
Lactate (sodium-)	-
Bromide (sodium-)	X
Iodide (sodium-)	X
Acetyltryptophane	-
Caprylic acid	-
Bicarbonate (HCO_3^-) @ low level	-
Bicarbonate (HCO_3^-) @ High level	-
Thiocyanate (sodium-)	X

Key

No clinically significant interference	-
Clinically significant interference	X

Table 12:Interference Values

Interferent	Maximum test concentration	Highest concentration level where interference was not significant	Impact on result for maximum test concentration
cCl^- (test level: 100 mEq/dL)			
Bromide	391 mg/dL	24.4 mg/dL	80.22 mEq/L
Iodide (sodium-)	45 mg/dL	11.25 mg/dL	11.57 mEq/L
Perchlorate ClO_4 (Potassium-)	20.8 mg/dL	15.6 mg/dL	6.35 mEqL
pH @low level	6.8	Dose-Response test not performed: The Chloride measurement is corrected for bicarbonate, calculated from pH and pCO_2. The pH interference on the Cl^- sensor will also depend on the pCO_2 level.	10.91 mEq/L
Thiocyanate (sodium-)	195 mg/dL	3.66 mg/dL	51.90 mmol/L
cCl^- (test level: 110 mEq/dL)			
Bromide	391 mg/dL	24.4 mg/dL	80.23 mEq/L
Iodide (sodium-)	45 mg/dL	11.25 mg/dL	12.12 mEq/L
Perchlorate ClO_4 (Potassium-)	20.8 mg/dL	No interference	Not applicable
pH @ low level	6.8	Dose-Response test not performed: The Chloride measurement is corrected for bicarbonate, calculated from pH and pCO_2. The pH interference on the Cl^- sensor will also depend on the pCO_2 level.	9.93 mEq/L
Thiocyanate (sodium-)	195 mg/dL	4.88 mg/dL	58.75 mEq/L

Conclusion

The results above demonstrate the acceptable analytical performance of the ABL90 FLEX PLUS System and its substantial equivalence to the predicate.