April 10, 2026

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

Re: K252207
Trade/Device Name: ABL90 FLEX PLUS System, safeCLINITUBES
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, GKR, JKA
Dated: March 10, 2026
Received: March 10, 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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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
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OHT7: Office of In Vitro Diagnostics
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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)*
K252207

Device Name
ABL90 FLEX PLUS System
safeCLINITUBES

Indications for Use *(Describe)*
The ABL90 FLEX PLUS System is an in vitro diagnostic, portable, automated analyzer that quantitatively measures:
-blood gas (pCO2) in heparinized arterial, venous and capillary whole blood, and
-pH and oximetry (ctHb) 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.

pH and pCO2: pH and pCO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

ctHb (Total Hemoglobin): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia in venous and arterial whole blood. Capillary whole blood is used to estimate the presence of ctHb.

safeCLINITUBES are intended for the collection, mixing, and dispensing of capillary whole blood samples on the ABL90 FLEX PLUS System.

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.

510(k) Summary – K252207

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

Submitter Information:

Company Name:	Radiometer Medical ApS
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Application Correspondent:

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Email:	andrea.swingle@radiometeramerica.com
Phone:	+1 510 246 2559

Date prepared: April 10, 2026

Device Information

Device Trade Name:	ABL90 FLEX PLUS System safeCLINITUBES
Common Name:	Blood Gas Analyzer
Regulations:	- 21 CFR 862.1120, *Blood gases (pCO_2, pO_2) and blood pH test system* - 21 CFR 864.5620, *Automated hemoglobin system* - 21 CFR 862.1675, *Blood specimen collection device*
Product Codes:	CHL, GKR, JKA
Device Class:	Class II

Predicate Device

Device Trade Name:	ABL90 FLEX PLUS
Common Name:	Blood Gas Analyzer
510(k)	K160153
Regulations:	- 21 CFR 862.1120, *Blood gases (pCO_2, pO_2) and blood pH test system* - 21 CFR 864.5620, *Automated hemoglobin system*
Product Codes:	CHL, GKR
Device Class:	Class II
Classification Panels:	Clinical Chemistry: CHL Hematology: GKR

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.

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

*safe*CLINITUBES are 70µL, 100µL and 125µL plastic capillary tubes with electrolyte-balanced heparin, mixing wires and end caps.

Intended Use

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

-blood gas (pCO_2) in heparinized arterial, venous and capillary whole blood, and
-pH and oximetry (*c*tHb) 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.

pH and *p*CO2: pH and *p*CO2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

*c*tHb (Total Hemoglobin): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia in venous and arterial whole blood. Capillary whole blood is used to estimate the presence of *c*tHb.

*safe*CLINITUBES are intended for the collection, mixing, and dispensing of capillary whole blood samples on the ABL90 FLEX PLUS System.

Substantial Equivalence Comparison

Table 1: Substantial Equivalence Comparison

	Subject device: ABL90 FLEX PLUS System (K252207)	**Predicate device: ABL90 FLEX PLUS (510(k) K160153)**
Manufacturer	Radiometer Medical ApS	Radiometer Medical ApS

	Subject device: ABL90 FLEX PLUS System (K252207)	Predicate device: ABL90 FLEX PLUS (510(k) K160153)
Intended Use/ Indications for Use	The ABL90 FLEX PLUS is a portable, automated system intended for in vitro testing that quantitatively measures: • Blood gas (pCO_2) in heparinized capillary, arterial, and venous whole blood • pH and oximetry (*c*tHb) in heparinized capillary whole blood	The ABL90 FLEX PLUS analyzer is an in vitro diagnostic, portable, automated analyzer that quantitatively measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized whole blood, and neonatal bilirubin in heparinized capillary, arterial and venous whole blood.
Intended use environment	Laboratory environment, near patient or point-of-care setting	Laboratory environment, near patient or point-of-care setting
Prescription/OTC Use	Prescription	Prescription
Sample requirements		
Sample type	Heparinized whole blood (arterial, venous, capillary)	Heparinized whole blood
Compatible sampling devices	Radiometer samplers (in S65 and C65 modes) and non-Radiometer samplers (in SP65 and C65 modes)	Radiometer samplers (in S65 and C65 modes) and non-Radiometer samplers (in SP65 and C65 modes)
Sample volume	65 µL	65 µL
Sample preparation	With balanced heparin anticoagulant	With balanced heparin anticoagulant
Device design		
Operating principles	Potentiometry: pH and pCO_2	Potentiometry: pH and pCO_2
	Spectrophotometry: *c*tHb	Spectrophotometry: *c*tHb
Consumables	• Sensor cassette • Solution pack	• Sensor cassette • Solution pack
Performance characteristics		
Reportable ranges	pH: 6.818 - 7.797	pH: 6.818 - 7.797
	pCO_2: 15.4-98.3 mmHg	pCO_2: 15.4-98.3 mmHg
	*c*tHb: 0.1 - 24.0 g/dL	*c*tHb: 0.1 - 24.0 g/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
pCO_2	9.40 - 99.89 mmHg
	1.25 - 13.32 kPa

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
pCO_2	mmHg	8.9
	kPa	1.19

N/A: Not applicable

Precision

Two 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

The primary endpoints of the study were repeatability and within laboratory precision for pooled across several sites. The sample material was Radiometer QUALICHECK5+ QC ampoules, a QC material that comes in four "levels". Testing occurred at three external sites. Table 4 presents the data on the primary and secondary endpoints.

Table 4: Precision results using QC materials

Parameter	QC ampoule	N	Mean	Repeatability		Within Lab Precision		Reproducibility	
				SD	CV%	SD	CV%	SD	CV%
pCO_2 (mmHg)	QC5+ L1	243	70.5	0.53	0.7	1.13	1.6	1.16	1.6
	QC5+ L2	244	42.7	0.23	0.5	0.5	1.2	0.50	1.2
	QC5+ L3	244	23.1	0. 12	0.5	0.27	1.2	0.29	1.2
	QC5+ L4	244	97.3	1.17	1.2	1.81	1.9	2.08	2.1

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

Precision using whole blood

Two precision studies were performed in whole blood, one in whole blood and one in capillary whole blood. The scope of the studies were (a) S65 and SP65 modes for testing pCO_2 and (b) C65 mode for testing pCO_2 and the four parameters previously cleared in arterial and venous whole blood. The primary endpoint of the study was repeatability, designated *SD*, pooled across sites. The values of *SD* and %CV were calculated for all levels and parameters. The following tables summarize the results of the study, separated to distinguish between parameters tested in S65 and SP65 modes (Table 5) and parameters tested in C65 mode (Table 6).

Table 5: Precision results using whole blood: pCO_2 in all modes

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
S65 Mode					
pCO_2 (mmHg)	4	25 - <32	27.775	0.320	1.15
	166	32 - <48	40.417	0.271	0.67
	50	48 - <60	52.030	0.266	0.51
	26	60 - <80	67.908	0.495	0.73
SP65 Mode					
pCO_2 (mmHg)	4	25 - <32	29.375	1.005	3.42
	160	32 - <48	40.448	0.168	0.42
	50	48 - <60	51.742	0.231	0.45
	27	60 - <80	68.989	0.334	0.48
C65 Mode					
pCO_2 (mmHg)	6	25 - <32	29.700	0.208	0.70
	166	32 - <48	40.627	0.304	0.75
	46	48 - <60	52.389	0.403	0.77
	30	60 - <80	69.787	1.217	1.74

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

Table 6: Precision results using capillary whole blood in C65 mode

Parameter (unit)	N	Test interval	Mean	Repeatability	
				SD	CV%
pH (none)	78	7.270-7.456	7.374	0.0125	0.2
pCO_2 (mmHg)	78	29.3-61.2	42.2	1.63	3.9
*c*tHb (g/dL)	76	8.6-17.1	13.6	0.26	1.9

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

Method comparison

Bias was determined based on an analysis of a method comparison study conducted in general accordance with CLSI EP09c, 3rd Edition, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.* The comparator device was one of two different versions of the ABL90 FLEX PLUS analyzer (in terms of its characteristics related to analytical

performance) depending on type of parameter, sample type and mode being analyzed. Table 7 lists the 510(k) clearance associated with the comparator device.

Table 7: Comparator device for each parameter

Parameter(s)	Sample type(s)	Mode(s)	510(k) associated with comparator device
pCO_2	Arterial, Venous, and Capillary	S65, SP65, C65	K160153
pH, *c*tHb	Capillary	C65	K240998

Analysis was performed by linear regression over the reportable range. Table 8 summarizes the results of the analysis for all blood types, modes, and sample types. Table 9 summarizes the results of arterial and venous blood combined for *p*CO_2.

Table 8: Method comparison results, all modes and sample types

Parameter	Blood type	Mode	n	Min-max	Intercept	Slope	R^2	MDLs	Bias at MDL
pCO_2 (mmHg)	A	S65	230	16.1-95	0.59	0.99	1.00	32	0.234
								48	0.054
		SP65	222	16.3-97.1	0.73	0.99	1.00	32	0.256
								48	0.021
	V	S65	239	16.1-95	0.55	0.99	1.00	32	0.177
								48	-0.007
		SP65	228	16.3-97.1	0.59	0.99	1.00	32	0.177
								48	-0.029
	C	C65	119	17-92.9	3.094	0.95	0.93	32	1.60
								48	0.85
pH	C	C65	115	6.87-7.78	-0.118	1.01	0.93	7.35	-0.01
								7.45	-0.01
*c*tHb (g/dl)	C	C65	110	0.36-22	0.713	0.99	0.95	7	0.66
								10	0.63
								17.5	0.57

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

Table 9: Method comparison results, arterial and venous combined, all medical decision levels

Parameter	n	Intercept	Slope	R^2	Medical decision point	Bias at MD
S65						
pCO_2 (mmHg)	446	0.55	0.99	1.0	32	0.20
					48	0.03
SP65						
pCO_2 (mmHg)	429	0.60	0.99	1.0	32	0.21
					48	0.02

Interference

Measurement of pCO_2 was tested for interfering substances 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*.* Paired-difference study was conducted on Intralipid, hemolysis, bilirubin (unconjugated and conjugated), biotin, and propofol, using clinically significant amount of the interferents. No interference was observed.

Conclusion

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