May 1, 2026

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

Re: K252488
Trade/Device Name: ABL90 FLEX PLUS System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Code: CGA
Dated: April 3, 2026
Received: April 3, 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
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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)*
K252488

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:
-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.

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 – K252488

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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Phone:	+1 510 246 2559

Date prepared: May 1, 2026

Device Information

Device Trade Name:	ABL90 FLEX PLUS System
Common Name:	Glucose test
Regulations:	21 CFR 862.1345*, Glucose test system*
Product Codes:	CGA
Device Class:	Class II

Predicate Device

Device Trade Name:	*i-STAT G* Cartridge with the *i-STAT 1 System*
Common Name:	Glucose test, analyzer, handheld
510(k)	K223755
Regulations:	21 CFR 862.1345, *Glucose test system*
Product Codes:	CGA
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:

- glucose 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:

- 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.

Substantial Equivalence Comparison

Table 1: Substantial Equivalence Comparison

	Subject device: **ABL90 FLEX PLUS System (K252488)**	**Predicate device:** ***i-STAT G* cartridge with the *i-STAT 1 System*** **(K223755)**
Manufacturer	Radiometer Medical ApS	Abbott
Intended Use/ Indications for Use	The ABL90 FLEX PLUS is an in vitro diagnostic, portable, automated system that quantitatively measures: • glucose in heparinized whole blood.	The i-STAT G cartridge with the i-STAT 1 System is intended for use in the in vitro quantification of glucose in arterial, venous, or capillary whole blood in point of care or clinical laboratory settings.
Intended use environment	Laboratory environment, near patient or point-of-care setting	Point of care or clinical laboratory
Prescription/OTC Use	Prescription	Prescription
Sample requirements		
Sample type	Heparinized capillary whole blood	Arterial, venous or capillary whole blood
Sample volume	65 µL	65 µL
Sample preparation	With balanced heparin anticoagulant	Capillary – with balanced heparin or lithium anticoagulant

	Subject device: **ABL90 FLEX PLUS System** **(K252488)**	**Predicate device:** ***i-STAT G* cartridge with the** ***i-STAT 1 System*** **(K223755)**
Device design		
Operating principles	Amperometry	Amperometry
Consumables	• Sensor cassette • Solution pack	Cartridge
Performance characteristics		
Reportable ranges	18-738 mg/dL	20-700 mg/dL

Analytical Performance Testing Summary

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

Precision in whole blood

Precision testing was performed in whole blood, in general accordance with CLSI EP05-A3, *Evaluation of Precision of Quantitative Measurement Procedures*. The scope of the precision study was testing in C65 mode for glucose in adult capillary whole blood. The primary endpoint of the study was within sample precision, designated *SD*, pooled across sites. The results of the study are summarized in Table 2.

Table 2: Precision using capillary whole blood

Parameter (unit)	**N**	**Test interval**	**Mean**	**Repeatability**	
				SD	**CV%**
*c*Glu (mg/dL)	78	88-275	147	3.6	2.5

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 by conducting a method comparison study in general accordance with CLSI EP09c, 3rd Edition, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.* The study compared capillary whole blood samples in C65 mode to arterial and venous whole blood samples in S65 mode (Table 3).

Table 3: Method comparison results comparing capillary samples (in C65 mode) to arterial and venous whole blood samples (in S65 mode)

Parameter	Comparator Blood Type	n	Min-max	Intercept	Slope	R^2	MDL 1	Bias at MDL 1
							MDL 2	Bias at MDL 2
*c*Glu (mg/dL)	A	114	37.2-684	-0.724	1.01	1.00	65	0.02
							200	1.57
	V	116	15.5-684	-0.206	1.01	0.97	65	0.17
							200	0.96

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

Conclusion

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