



June 18, 2026

Daxor Corporation
Jonathan Feldschuh
Chief Scientific Officer
107 Meco Ln.
Oak Ridge, Tennessee 37830

Re: K261099

Trade/Device Name: Blood Volume Analyzer (200)
Regulation Number: 21 CFR 864.5950
Regulation Name: Blood volume measuring device
Regulatory Class: Class II
Product Code: JWO
Dated: May 20, 2026
Received: May 20, 2026

Dear Jonathan Feldschuh:

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,

Takeesha Taylor-Bell

Takeesha Taylor-Bell
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K261099

Device Name

Blood Volume Analyzer (200)

Indications for Use (Describe)

The Daxor BVA-200® is an automated system that is used to measure/calculate the red cell mass (mL), plasma volume (mL) and total blood volume (mL), along with the related deviations from ideal values by amount (mL) and percentage (%) in adults. In addition, the Normalized Hematocrit (%) and Albumin Transudation Rate (%/min) are calculated. It is an in vitro medical device composed of a microprocessor, software, touchscreen, and gamma counter and accessory convenience kit.

The Daxor BVA-200 is intended to calculate human blood volumes by the method of tracer diffusion (Indicator dilution technique) with I-131 as the tracer after injection of I-131 Human Serum Albumin. The Daxor BVA-200 provides a Quantitative Assessment of total blood and plasma volumes using an automated system.

Data inputs to the software come from the measured characteristics of patient venous whole blood samples collected in K3EDTA vacutainer tubes (hematocrit and tracer concentration) and tracer calibration standards. The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program. The package also calculates the patient expected (or ideal) blood volume from physical parameters. Hyper- or hypovolemia, and associated red cell volumes are reported, with statistics showing the quality of the results.

For in vitro diagnostic use in a Clinical Laboratory setting and operated by laboratory technicians.

Rx use only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Daxor Corporation
107 Mecco Lane
Oak Ridge, TN 37803

Phone: 865-425-0555
Fax: 865-425-0551

Contact Person: Jonathan Feldschuh
Date Prepared: July 30, 2025

II. DEVICE

Name of Device: Blood Volume Analyzer
Common or Usual Name: BVA-200
Regulatory Class: Class 2
Product Code: JWO

III. PREDICATE DEVICE

Daxor BVA-200, K251087
This predicate has not been subject to a design-related recall

IV. DEVICE DESCRIPTION

The Daxor BVA-200 is an automated system that is used to calculate the red cell mass, plasma volume and total blood volume. It is an in vitro medical device composed of a microprocessor, software, touchscreen, and gamma counter. The accessory convenience kit includes single-use whole blood cartridges and protective sleeves.

The Daxor BVA-200 is designed to calculate human blood volume, using the method of tracer dilution, utilizing tagged serum albumin (I-131, resulting in "I-HSA"). Data inputs to the software come from the measured characteristics of patient blood samples, the patient's documented hematocrit, manufacturer's labeled tracer concentration, and tracer calibration standards. The software package also calculates the patient expected (or ideal) blood volume from physical parameters of height, weight, and sex that are provided to the laboratory in the labeling of the whole blood samples. Hyper- or hypovolemia, and associated red cell volumes, are reported, with statistics showing the quality of the results for evaluation by the clinician.

The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program.

The BVA-200 has a touchscreen for operator interaction, and provides clear instructions and prompts for the steps necessary for performing the test.

V. INDICATIONS FOR USE

The Daxor BVA-200® is an automated system that is used to measure/calculate the red cell mass (mL), plasma volume (mL) and total blood volume (mL), along with the related deviations from ideal values by amount (mL) and percentage (%) in adults. In addition, the Normalized Hematocrit (%) and Albumin Transudation Rate (%/min) are calculated. It is an in vitro medical device composed of a microprocessor, software, touchscreen, and gamma counter and accessory convenience kit.

The Daxor BVA-200 is intended to calculate human blood volumes by the method of tracer diffusion (Indicator dilution technique) with I-131 as the tracer after injection of I-131 Human Serum Albumin. The Daxor BVA-200 provides a Quantitative Assessment of total blood and plasma volumes using an automated system.

Data inputs to the software come from the measured characteristics of patient venous whole blood samples collected in K3EDTA vacutainer tubes (hematocrit and tracer concentration) and tracer calibration standards. The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program. The package also calculates the patient expected (or ideal) blood volume from physical parameters. Hyper- or hypovolemia, and associated red cell volumes are reported, with statistics showing the quality of the results.

For in vitro diagnostic use in a Clinical Laboratory setting and operated by laboratory technicians.

Rx use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

There is no change in the technological characteristics of the proposed current BVA-200 (K261099) differs from the BVA-200 (K251087) in that the BVA-200 can evaluate and calculate blood volume based on whole blood; incorporates a Mil Spec rugged tablet computer that uses a touch screen display for patient data; can be battery powered as well as main powered; and can be loaded and carried in a custom portable (intended for clinical laboratory use only) Pelican case. The

gamma count data for each sample are generated automatically by the BVA-200 when the operator inserts the labeled sleeve containing the filled custom Whole Blood Container into the custom aperture, enters the time of blood draw (or confirms the time prompted by the device if the operator has confirmed the time is contemporaneous with the device's internal clock), and activates the gamma counter on a screen prompt. If the time of blood draw differs from current, the BVA-200 will accommodate the extended time span by 'discounting' the gamma count rate by the known rate of decay from actual time of blood draw to actual time of gamma concentration measurement.

Device & Predicate Device(s):	<u>Device</u> <u>K261099</u>	<u>Predicate</u> <u>K251087</u>
Device Trade Name	Blood Volume Analyzer (200)	Blood Volume Analyzer (200)
Intended Use / Indications for Use	<p>The Daxor BVA-200® is an automated system that is used to measure/calculate the red cell mass (mL), plasma volume (mL) and total blood volume (mL), along with the related deviations from ideal values by amount (mL) and percentage (%) in adults. In addition, the Normalized Hematocrit (%) and Albumin Transudation Rate (%/min) are calculated. It is an in vitro medical device composed of a microprocessor, software, touchscreen, and gamma counter and accessory convenience kit.</p> <p>The Daxor BVA-200 is intended to calculate human blood volumes by the method of tracer diffusion (Indicator dilution technique) with I-131 as the tracer after injection of I-131 Human Serum Albumin. The Daxor BVA-200 provides a Quantitative Assessment of total blood and plasma volumes using an automated system.</p> <p>Data inputs to the software come from the measured characteristics of patient venous whole blood samples collected in K3EDTA vacutainer tubes (hematocrit and tracer concentration) and tracer calibration standards. The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program. The package also calculates the patient expected (or ideal) blood volume from physical parameters. Hyper- or hypovolemia, and associated red cell volumes are reported, with statistics showing the quality of the results.</p> <p>For in vitro diagnostic use in a Clinical Laboratory setting and operated by laboratory technicians.</p> <p>Rx use only.</p>	Same
Principle of Operation	Indicator Dilution method	Same
General Device Characteristic Differences		

Device & Predicate Device(s):	<u>Device</u> <u>K261099</u>	<u>Predicate</u> <u>K251087</u>
Operator	Clinical Laboratory Technician	Nuclear Medical Technician (NucMed Tech)
Instructions for Use	<p>Instructions for Use (IFU) include pre-analytical steps of sample acceptance (purple top tube; patient and sample information, fill of whole blood containers and operation of the device in the clinical laboratory environment ending with report production. IFU was re-organized into sections of Introductory Materials (e.g., indication), Technical Information for Laboratorian, Detailed Operational Information for Operator, and Miscellany. Verification and Validation per design controls on re-organization performed.</p>	<p>Same</p> <p>Instructions for Use included instructions on administration of I-131 labeled Human Serum Albumin per labeling of MEGATOPE/Volumex® (BLA 017837) which are now deleted as not relevant to the operation of the device in a clinical laboratory and not directed to the Laboratorian responsible for device operation.</p>
Operator Requirements	<p>Knowledge, Skills, and Abilities required of a Clinical Laboratory Technician operating in a CLIA-certified laboratory environment. The radiation level in the blood samples measured is below 1 microcurie, which is not distinguishable from background and thus falls below the Nuclear Regulatory Commission's threshold of regulatory concern. This level of exposure is exempt from occupational monitoring under NRC guidelines, indicating no significant radiological safety concerns for handling or disposal. Specimens may be discarded, after their retention time, as standard medical waste in a biohazard container.</p>	<p>Knowledge, Skills, and Abilities required of NucMed Tech under Radioactive Materials License (RAML)</p> <p>The institution's RAML encompasses all uses of radionuclear products within that facility, including specimen analysis for the BVA-100 at POC sites.</p>

Device & Predicate Device(s):	Device <u>K261099</u>	Predicate <u>K251087</u>	
General Device Characteristic Similarities			
Tracer	I-131 labeled Human Serum Albumin	Same	
Radiation emitted by device	None (for radiation emitted by disposable samples placed in device). Gamma (“Geiger”) counters do not emit radiation but only detect radiation. Further, the shielding around the detector itself is designed to isolate the gamma counter from ambient or external radiation to permit counting samples of low activity (improve signal to noise ratio).	Same	
Values Reported	Total Blood Volume (TBV), Red Cell Volume (RCV), Plasma Volume (PV), along with patient-specific norms and deviations there from	Same	
Reference Range	TBV	-8 to +8	Same
	RCV	-10 to +10	
	PV	-8 to +8	
	ATR	0 to 0.25	
	nHct	37 - 41 (females) 40 - 46 (males)	
Accuracy	Blood Volume computed with > 95% Accuracy Results with 5 sequential timed human specimens	Same	
Number of Samples	Total of up to 5 samples plus baseline sample	Same	
Scintillation Counter	Scintillates on bombardment with gamma rays	Same	
Disposal of Test Materials	Blood and plasma samples and disposables are of such low activity (less than 0.05 µCi) that they are not distinguishable from	Same	

Device & Predicate Device(s):	<u>Device K261099</u>	<u>Predicate K251087</u>
	background with a normal Geiger counter and are permissibly disposed under radiation safety rules as normal biological safety, medical / sharps disposal. No special handling is required for patient bodily fluids (urine. etc.) or clothing.	
Detection of Radiation Contamination	Integrated QC procedures detect abnormal background counts when well is empty and thus preclude the possibility of carryover.	Same
Remediation of Radiation Contamination	Detector well is sealed aluminum space which can be cleaned with a range of solvents.	Same
Calculation of Transudation Rate (Capillary Leakage)	If more than 2 samples are used, the transudation rate can be calculated if ordered rather than using the assumed 0.25%/min	Same
Quality Control	Integrated Procedures	Same
Report Available	Onscreen Printed via attached printer Downloaded as file via thumb drive	Same
Sample Type	Whole Blood	Same
Phlebotomy volume required	Minimum 2.5 mL blood	Same
Sample size	1.8 mL	Same
Shielding	Tungsten	Same
Crystal Material and Gamma Detection	CsI	Same
Photomultiplier	Photomultiplier silicon	Same
Sample Preparation for Counting	Whole blood collection cartridge (WBCC) is filled via syringe of patient sample. The cartridge design assures highly	Same

Device & Predicate Device(s):	<u>Device</u> <u>K261099</u>	<u>Predicate</u> <u>K251087</u>
	accurate volumes during the fill process. We recommend refrigeration of samples if not counted within 4 hours of collection although shipping and other testing demonstrates that, once the whole blood cartridge is filled, any degradation or hemolysis will not change the radiation emission which is based solely on the volume of blood and not the condition of the blood.	
Software	Algorithm to ‘back’ compute whole blood volume from scintillation counts from I131 diluted in whole blood for which an aliquot after dilution it taken	Same.
Samples Introduced to gamma counter	Directly by operator, in response to software prompts.	Same
User Interaction	Integrated Touchscreen (6” diagonal)	Same

VII. PERFORMANCE DATA

Performance of the revised instructions were verified and validated per design validation pursuant to QMSR. In the validation protocol, 5 operators with the requisite clinical laboratory experience were provided with the revised IFU, the BVA-200, and samples and evaluated to identify whether the revised IFU conformed to defined user needs and intended uses as outlined in the Sponsor’s Product Requirements and Risk Analysis. Each relevant user need, requiring validation, was identified and addressed to ensure that it meets the intended user need. Protocol testing was integrated into the daily workflow where the operators are often multitasking between testing and other duties. A Patient Sample Record was provided to the User, along with a VOPS set. The revised BVA-200 IFU met the acceptance criteria for the User Validation.

VIII. CONCLUSIONS

The validation data and performance support the safety of the device and the substantial equivalence to the predicate for the same intended use. Design verification and validation testing demonstrates that the revised IFU for the BVA-200 device should perform as intended in the specified use conditions.