August 4, 2025

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

Re: K251087
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: July 3, 2025
Received: July 3, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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 -S

Takeesha Taylor-Bell
Deputy Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251087

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.

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510(k) Summary

I. SUBMITTER

Daxor Corporation
107 Meco 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-100, K964406
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 (hematocrit and tracer concentration) and tracer calibration standards. 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.

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

The proposed BVA-200 differs from the BVA-100 in that the BVA-200 can evaluate and calculate blood volume based on whole blood rather than requiring plasma fractionation (centrifugation and pipetting); incorporates a Mil Spec rugged tablet computer that uses a touch screen display for patient data entry in place of the 1990s era desktop computer, separate keyboard and monitor; has enhanced automated internal Quality Control; can be battery powered as well as main powered; and can be loaded and carried in a custom portable 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.

Both devices are capable of detecting I-131 concentrations quantitatively based on the known rate of gamma emissions from radioactive decay which is tightly concentration dependent. The source of I-131 in the original injectate is, after dilution, present in the quantities needed and thus will readily register against background for both detectors, with the number of counts scaling linearly with activity and the error scaling as the square root of activity. This is the counting statistical behavior required for the indicator dilution technique mathematics which is identical between the BVA-100 and BVA-200 or, indeed, the labeling of the approved radio-iodinated albumin (BLA 017837). If the time of blood draw differs from current, both devices 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.

The BVA-100 predicate device is designed to automatically count a series of precision pipetted aliquots of patient plasma, which are placed in the carousel mechanism, and introduced into the detector well as the carousel moves under computer control. The time of measurement of radiation will be slightly different from the time of specimen withdrawal. Since both times are entered, the marginal decrease in radiation release based on decay of the tracer can be calculated and the algorithm can adjust for this time spread. The BVA-200 provides the same capability of delayed measurement at up to 48 hours.

Device & Predicate Device(s):	Device K251087	Predicate K964406
Device Trade Name	Blood Volume Analyzer (200)	Automated Multi-Point Blood Volume Analyzer
General Device Characteristic Similarities		
Intended Use/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	The Daxor BVA-100 is a software package designed to calculate human blood volume, using the method of tracer dilution, utilizing tagged serum albumin (a commonly used tag is I-131, resulting in "I-HSA"). Data inputs to the software come from the measured characteristics of patient blood samples (hematocrit and tracer concentration) and tracer calibration standards. The package

Device & Predicate Device(s):	Device K251087	Predicate K964406
	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.	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. The patient blood samples and the calibration standards are measured in a gamma counter, whose output is automatically input to this calculation program.

Device & Predicate Device(s):	Device K251087	Predicate K964406
Principle of Operation	Indicator Dilution method	Same
Operator	Nuclear Medical Technician (NucMed Tech)	Same
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	Same
Scintillation Counter	Scintillates on bombardment with gamma rays	Same
Patient exposure to radiation	I-131 dose is limited to maximum activity of 25 microcuries (µCi). The EDE from a 25µCi dose is 101 rem, which is roughly the same as the annual exposure from naturally occurring sources of radiation (excluding radon) at sea level.	Same
Operator exposure to radiation	Operator (Nuclear Medical technician) is exposed to very small fraction (approximately 1/1000) of patient radiation during procedure,	Same

Device & Predicate Device(s):	Device K251087	Predicate K964406
	based on time handling dose and in proximity to patient. Nuclear Medical technicians are monitored for exposure to radiation.	
Quality Control	Integrated Procedures	Same
Report Available	Onscreen Printed via attached printer Downloaded as file via thumb drive	Same
Total Blood Volume	The BVA-200 software will report the total blood volume with results that range from 1,700 mL to 14,500 mL as a function of the patient's true blood volume calculated by radio diffusion.	Same
General Device Characteristic Differences		
Sample Type	Whole Blood	Plasma
Phlebotomy volume required	3 mL blood	6 mL blood
Sample size	1.8 mL	1 mL
Shielding	Tungsten	Lead
Gamma Detection	Smaller Crystal size and material- counts fewer emissions, linearly corrected mathematically	Larger Crystal size and material - counts more emissions
Crystal Material	CsI advantages increased moisture resistance and plastic deformation rather than cracking	NaI
Photomultiplier	Photomultiplier silicon	Photomultiplier tube
Mitigation of Radiation Contamination	Samples are introduced into detector well inside disposable plastic sleeves.	Samples are placed in plastic drop tubes of sample changer. If drop

Device & Predicate Device(s):	Device K251087	Predicate K964406
		tubes become contaminated, they can be cleaned or swapped out.
Samples Introduced to gamma counter	Directly by operator, in response to software prompts.	Aliquots are placed in a carousel according to designated pattern indicated on device, and carousel sequentially delivers them to the gamma counter well.
User Interaction	Integrated Touchscreen (6" diagonal)	Attached Windows based computer & keyboard

VII. PERFORMANCE DATA

Performance of the BVA-200 was validated in a clinical comparison study with the predicate BVA-100 device, using blood derived from patients undergoing blood volume measurement with the BVA-100 as part of their clinical treatment or as part of a research study. A total of 319 unique, independent, comparable measurements were recorded. This study demonstrated robust and clinically meaningful substantial equivalence. This study also demonstrated that the effects of matrix in whole blood (K3EDTA anticoagulant) are no different with the BVA-200 than with the BVA-100, which is cleared for marketing and analysis of blood volumes using the anticoagulated plasma fraction.

The following table shows the results for Passing-Bablok and Deming Regressions for the Instrument vs Comparator (BVA-200 vs. BVA-100):

Measure	Regression	N	Slope (95% CI)	Intercept (95% CI)	Pearson correlation coefficient
TBV	Passing-Bablok	319	1.031 (1.014 to 1.049)	-138 (-235 to -59)	0.99
TBV	Deming	319	1.033 (1.017 to 1.050)	-153 (-241 to -69)	0.99
RCV	Passing-Bablok	319	1.016 (1.002 to 1.030)	-25 (-50 to 2)	0.99

RCV	Deming	319	1.024 (1.008 to 1.040)	-37 (-68 to -10)	0.99
PV	Passing-Bablok	319	1.033 (1.016 to 1.051)	-99 (-155 to -46)	0.99
PV	Deming	319	1.029 (1.014 to 1.046)	-83 (-138 to -32)	0.99
nHct	Passing-Bablok	319	1.007 (0.982 to 1.032)	-0.19 (-1.18 to 0.77)	0.98
nHct	Deming	319	1.022 (0.999 to 1.047)	-0.76 (-1.71 to 0.21)	0.98

This study also confirmed the reference range of the ideal (patient normal) values for the calculated volumes (which are based on calculations detailed in reference 9):

Reference Status	Normal	Has Medical Condition
N	22	41
Age	36.7 ± 16.5	53.8 ± 16.8
Sex	Female = 59% Male = 41%	Female = 24% Male = 76%
Inpatient / Outpatient	Outpatient Subject = 100%	Outpatient Subject = 54% Inpatient Subject = 46%
Hct	41.3 ± 3.1	39.5 ± 5.91
Deviation from Ideal Weight (%)	26.9% ± 33.7%	40.2% ± 30.5%
Ideal TBV	4860 ± 655	5430 ± 848
Ideal RCV	1850 ± 328	2150 ± 397
Ideal PV	3010 ± 352	3280 ± 466
BVA200_TBV	4950 ± 808	5770 ± 1420
BVA200_RCV	1850 ± 357	2030 ± 507
BVA200_PV	3110 ± 497	3730 ± 1070
BVA200_SD	0.0196 ± 0.0107	0.0154 ± 0.00641
BVA200_Slope (%/min)	0.205% ± 0.070%	0.197% ± 0.076%

Reference Status	Normal	Has Medical Condition
BVA200_TBV Deviation from patient Ideal (%)	+1.75% ± 7.77%	+5.72% ± 15.8%
BVA200_RCV Deviation from patient Ideal (%)	-0.13% ± 8.29%	-5.40% ± 15.3%
BVA200_PV Deviation from patient Ideal (%)	+3.07% ± 10.5%	+13.1% ± 23.2%

The following table shows the results of the reference range study, along with the categories listed in the BVA report. The study confirmed that the reference range is accurate.

Value	Normal Range	Normal Females (N=13)	Normal Males (N=9)
TBV	-8 to +8	0.529 ± 0.09	3.52 ± 5.58
RCV	-10 to +10	0.95 ± 8.39	-1.69 ± 8.39
PV	-8 to +8	0.291 ± 11.9	7.07 ± 6.78
ATR	0 to 0.25	0.179 ± 0.0608	0.242 ± 0.0692
nHct	37 - 41 (females) 40 - 46 (males)	39.0 ± 4.53	44.2 ± 3.74

Value	Normal	Mild	Moderate	Severe	Extreme
TBV (absolute dev %)	0 to 8	>8 to 16	>16 to 24	>24 to 32	>32
RCV (absolute dev %)	0 to 10	>10 to 20	>20 to 30	>30 to 40	>40
PV (absolute dev %)	0 to 8	>8 to 16	>16 to 24	>24 to 32	>32

Value	Normal	Elevated	High	Very High
ATR (%/min)	0 to 0.25	0.25 to 0.40	0.40 to 0.50	> 0.50

Precision: Venous whole blood samples were obtained from male and female volunteers. Samples were spiked with various amounts of radio-iodinated albumin using Volumex to duplicate representative high (30 microCuries/mL radio-diluted in 2727mL of blood volume) and low (25 microCuries/mL diluted in 6250 mL of blood volume) ranges encountered by the BVA-100. Reference samples without radio-iodinated albumin were also prepared. A set of samples were diluted with plasma to reduce the hematocrit by 10% – thus a range of baseline hematocrits from approximately 40% to approximately 50% is expected plus a set with a range from 30% to 40%. Indeed, while testing of radiation equipment is more typically done with check samples without blood contents, the addition of blood contents permits a thorough performance evaluation.

Testing was conducted to assess relative precision in gamma radiation, TBV, PV, RCV, and nHCT in both the BVA-100 and BVA-200. Comparison of measurements taken at different times, under different conditions, and by different operators where the same sample was run in different settings demonstrated no substantial effect on results.

The following tables show the precision results for the BVA-200. All total precision percentage coefficient of variation results were below 3.6%.

BVA-200 TBV

Sample			Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
	N	Mean Value	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	989	16.7	1.69	0.1	0.01	14.3	1.45	2.0	0.20	4.2	0.42	3.3	0.33	22.71	2.30
Sample (HIGH_Vol_15000)	64	14,322	379.6	2.65	14.2	0.10	186.6	1.30	42.7	0.30	93.7	0.65	101.2	0.71	447.17	3.12
Sample (HIGH_Vol_2500)	64	2,443	51.6	2.11	4.6	0.19	36.6	1.50	6.9	0.28	12.3	0.50	20.1	0.82	68.02	2.78
Sample (HIGH_Vol_5000)	64	4,967	120.6	2.43	6.6	0.13	101.1	2.04	42.4	0.85	40.0	0.81	10.5	0.21	168.28	3.39
Sample (HIGH_Vol_7500)	64	7,392	173.3	2.34	1.7	0.02	106.0	1.43	23.8	0.32	52.6	0.71	60.6	0.82	219.72	2.97
Sample (LOW_Vol_1000)	64	1,108	13.8	1.25	1.3	0.12	14.1	1.27	4.3	0.39	2.8	0.25	3.7	0.33	20.76	1.87
Sample (LOW_Vol_15000)	64	16,133	353.9	2.19	50.1	0.31	79.9	0.50	107.9	0.67	115.2	0.71	81.9	0.51	407.14	2.52

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (LOW_Vol_2500)	64	2,747	68.6	2.50	2.1	0.08	31.3	1.14	15.5	0.56	1.7	0.06	22.4	0.82	80.22	2.92
Sample (LOW_Vol_5000)	64	5,419	104.6	1.93	8.0	0.15	84.1	1.55	17.7	0.33	33.8	0.62	26.2	0.48	142.20	2.62
Sample (LOW_Vol_7500)	64	6,925	151.0	2.18	1.0	0.01	84.1	1.21	63.7	0.92	7.3	0.11	47.6	0.69	190.40	2.75

BVA-200 RCV

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	536	9.0	1.68	0.0	0.00	7.8	1.46	1.1	0.21	2.3	0.43	1.9	0.35	12.33	2.30
Sample (HIGH_Vol_15000)	64	7,984	211.6	2.65	7.9	0.10	104.0	1.30	23.8	0.30	52.2	0.65	56.4	0.71	249.25	3.12
Sample (HIGH_Vol_2500)	64	1,343	28.4	2.11	2.6	0.19	20.1	1.50	3.8	0.28	6.7	0.50	11.2	0.83	37.44	2.79
Sample (HIGH_Vol_5000)	64	2,763	67.1	2.43	3.7	0.13	56.3	2.04	23.7	0.86	22.2	0.80	5.8	0.21	93.67	3.39
Sample (HIGH_Vol_7500)	64	4,121	96.6	2.34	0.9	0.02	59.1	1.43	13.2	0.32	29.3	0.71	33.8	0.82	122.48	2.97
Sample (LOW_Vol_1000)	64	186	2.3	1.24	0.2	0.11	2.4	1.29	0.7	0.38	0.4	0.22	0.6	0.32	3.48	1.87
Sample (LOW_Vol_15000)	64	2,834	62.2	2.19	8.8	0.31	14.0	0.49	19.0	0.67	20.2	0.71	14.5	0.51	71.57	2.53
Sample (LOW_Vol_2500)	64	464	11.6	2.50	0.3	0.06	5.3	1.14	2.6	0.56	0.3	0.06	3.8	0.82	13.57	2.92
Sample (LOW_Vol_5000)	64	928	17.9	1.93	1.4	0.15	14.4	1.55	3.0	0.32	5.8	0.62	4.4	0.47	24.33	2.62

Sample			Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
Sample (LOW_Vol_7500)	64	1,146	25.0	2.18	0.2	0.02	13.9	1.21	10.5	0.92	1.2	0.10	7.9	0.69	31.50	2.75

BVA-200 PV

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	453	7.6	1.68	0.0	0.00	6.6	1.46	0.9	0.20	1.9	0.42	1.5	0.33	10.39	2.29
Sample (HIGH_Vol_15000)	64	6,339	168.0	2.65	6.3	0.10	82.5	1.30	18.9	0.30	41.4	0.65	44.8	0.71	197.86	3.12
Sample (HIGH_Vol_2500)	64	1,101	23.2	2.11	2.0	0.18	16.5	1.50	3.1	0.28	5.5	0.50	9.1	0.83	30.61	2.78
Sample (HIGH_Vol_5000)	64	2,204	53.5	2.43	3.0	0.14	44.9	2.04	18.9	0.86	17.7	0.80	4.7	0.21	74.70	3.39
Sample (HIGH_Vol_7500)	64	3,271	76.7	2.34	0.8	0.02	47.0	1.44	10.5	0.32	23.3	0.71	26.8	0.82	97.28	2.97
Sample (LOW_Vol_1000)	64	922	11.5	1.25	1.1	0.12	11.7	1.27	3.6	0.39	2.3	0.25	3.0	0.33	17.25	1.87
Sample (LOW_Vol_15000)	64	13,299	291.7	2.19	41.3	0.31	65.8	0.49	89.0	0.67	95.0	0.71	67.6	0.51	335.62	2.52
Sample (LOW_Vol_2500)	64	2,283	57.1	2.50	1.7	0.07	26.0	1.14	12.8	0.56	1.4	0.06	18.6	0.81	66.72	2.92
Sample (LOW_Vol_5000)	64	4,492	86.6	1.93	6.7	0.15	69.7	1.55	14.7	0.33	28.1	0.63	21.6	0.48	117.79	2.62
Sample (LOW_Vol_7500)	64	5,778	126.0	2.18	0.8	0.01	70.2	1.21	53.2	0.92	6.1	0.11	39.8	0.69	158.92	2.75

BVA-200 nHct

Sample	N	Mean Value	Repeatability (Within-Run)		Between-Run		Between-Day		Between-Operator		Between-Instrument		Between-Calibrator		Reproducibility Total Precision	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Sample (HIGH_Vol_1000)	64	12	0.2	1.67	0.0	0.00	0.2	1.67	0.0	0.00	0.1	0.83	0.0	0.00	0.30	2.50
Sample (HIGH_Vol_15000)	64	175	4.7	2.69	0.2	0.11	2.3	1.31	0.5	0.29	1.2	0.69	1.2	0.69	5.53	3.16
Sample (HIGH_Vol_2500)	64	29	0.6	2.07	0.1	0.34	0.4	1.38	0.1	0.34	0.2	0.69	0.2	0.69	0.79	2.72
Sample (HIGH_Vol_5000)	64	61	1.5	2.46	0.1	0.16	1.2	1.97	0.5	0.82	0.5	0.82	0.1	0.16	2.05	3.36
Sample (HIGH_Vol_7500)	64	90	2.1	2.33	0.0	0.00	1.3	1.44	0.3	0.33	0.6	0.67	0.7	0.78	2.65	2.95
Sample (LOW_Vol_1000)	64	4	0.1	2.50	0.0	0.00	0.1	2.50	0.0	0.00	0.0	0.00	0.0	0.00	0.14	3.54
Sample (LOW_Vol_15000)	64	62	1.4	2.26	0.2	0.32	0.3	0.48	0.4	0.65	0.4	0.65	0.3	0.48	1.58	2.55
Sample (LOW_Vol_2500)	64	10	0.3	3.00	0.0	0.00	0.1	1.00	0.1	1.00	0.0	0.00	0.1	1.00	0.35	3.46
Sample (LOW_Vol_5000)	64	20	0.4	2.00	0.0	0.00	0.3	1.50	0.1	0.50	0.1	0.50	0.1	0.50	0.53	2.65
Sample (LOW_Vol_7500)	64	25	0.6	2.40	0.0	0.00	0.3	1.20	0.2	0.80	0.0	0.00	0.2	0.80	0.73	2.91

Linearity

Multiple samples were measured in both the BVA-100 and BVA-200 to assess both linearity and bias at the high and low measurements. The following results were obtained from the data in the method comparison study:

	N	Mean Expected	Mean Observed	SD	CV Percent	Global Slope	Mean Bias Percent	CI Lower	CI Upper
TBV	319	5323	5348	170	3.24	1.02	0.41	5088	5608
RCV	319	1905	1912	56	3.00	1.01	0.38	1828	1996
PV	319	3417	3433	105	3.11	1.02	0.37	3275	3590
nHCT	319	40.14	40.27	1.22	3.00	1.00	0.37	38.43	42.11

An additional study using contrived samples was performed to verify linearity and absence of bias at very high and low volume measurements (2000 ml to 18000 ml). The coefficient of variation (CV) for repeatability was ≤5% for all measured parameters across the tested concentration range. The maximum deviation from linearity was ≤8% for all measured parameters across the tested concentration range, as determined by comparison to a linear regression model. In conclusion, there is no clinically meaningful deviation from linearity.

Carryover

Analysis of the impact of a preceding high level spiked sample on the values of a following low level spiked sample were conducted for the BVA- 200 analyses of radiation emission. Sufficient high-level samples immediately followed by low-level samples by the same operator and with the same equipment were utilized to assess the potential for carryover. There was no carryover observed.

Be sure that blood is not spilled in the sample port. Clean as necessary. QC checks will demonstrate contamination if any. There was no carryover observed in testing.

Sample Stability

The spiked venous whole blood stability, settling, FEDEX shipping study, and non-level positioning demonstrate that the gamma emission from a fixed amount of blood is impervious to temperature and humidity; that the decrease in radiation emission over time corresponds to the known decrease in radiation from the isotope in question (I-131); that the WBCC can withstand shipping; that the BVA-200 operates in a non-level position up to 15 degrees in any direction; and that settling does not affect gamma emissions read by the gamma counter scintillator inside the BVA-200.

Stability testing was performed on whole blood cartridges that were first measured, then allowed to settle in either refrigerated or room temperature conditions for a period up to four days. Samples were recounted at 18, 24, 48, and 120 hours in both agitated and settled states. Contrived samples were used that covered a wide range of possible Hct and volume values. No significant differences were observed, nor was there any significant drift of measurements observed. The study performed validates the measurement of cartridges up to 4 days of stability at refrigerated (4ºC/ 40ºF) and room temperature (22ºC/ 72ºF).

Handling Testing

A cartridge drop test was performed. The results validated that the cartridges still met all performance criteria after cartridges were dropped from a height of 48 inches onto a hard surface. None of the average measured parameters of the test differed from the pre-drop measurements by more than 2.7%.

A simulated shipping & handling study was performed to assess resistance to breakage and radio-emission stability in a standardized shipping stress testing (Study ISTA-3A). This includes testing for temperature, humidity, vibration, and shock. As with the settling study, this study demonstrated that, once filled, the whole blood cartridge emission rate performs as expected for the volume and concentration of radioisotope. The testing validated sample integrity after shipping blood in a vacutainer tube, sample integrity after shipping blood in a cartridge, sample integrity after shipping a cartridge from a shipped vacutainer, and device integrity after shipping a device and a shipping cartridge. None of the average measured parameters of the test differed from the pre-ship measurements by more than 3.1%.

Tilt position – Testing established that the measurement of the analyte concentration (I-131 gamma emission) from the venous whole blood sample is stable notwithstanding non-level positioning at 15 degrees in any direction. None of the average measured parameters of the test differed from the pre-ship measurements by more than 3.1%.

Interference

A hemolysis interference study was performed. Hemolysis is a common interferant in medical diagnostic tests involving measuring analytes in blood. A study was performed with contrived samples to compare the BVA-200 reported parameters across three hemolysis levels. Baseline samples were verified to have no hemolysis. Partial hemolysis was induced by subjecting blood samples to a partial freezing cycle at -20C. Gross hemolysis was induced by subjecting the partially hemolyzed blood samples to an additional complete freezing cycle (until completely frozen) at -20C. Level of hemolysis was verified by three independent methods (colorimetric matching, quantification of fluorescent absorption at 540 nm, and Hct measurement). Ten independent samples were used, with volume values measured after partial hemolysis and gross hemolysis compared to the baseline (no hemolysis). Results for all parameters (TBV, PV, RCV, and nHct) were not affected by hemolysis: the difference between the partial hemolysis values and the no hemolysis values were - 0.72% ± 0.77%, expressed as a percentage of the baseline no hemolysis values; and gross hemolysis values were - 0.14% ± 2.16%, expressed as a percentage of the baseline no hemolysis values.

VIII. CONCLUSIONS

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