July 8, 2026

BlueDop Medical, Ltd.
Jorge Millan
Regulatory Consultant
Sigma Biomedical
490 Sawgrass Corporate Pkwy.
Suite 130
Sunrise, Florida 33325

Re: K260700
Trade/Device Name: BlueDop Vascular Expert (BVE)
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: June 8, 2026
Received: June 9, 2026

Dear Jorge Millan:

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); 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,

STEPHEN C. BROWNING -S

CDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
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)*
K260700

Device Name
BlueDop Vascular Expert (BVE)

Indications for Use *(Describe)*
The BlueDop Vascular Expert (BVE) is intended to non-invasively detect the presence of blood flow in peripheral arteries using Doppler ultrasound technology. The device provides Doppler waveform information to support clinical evaluation of peripheral vascular status.
The BVE is intended to be used as an adjunct to standard clinical assessment and does not provide a standalone diagnostic determination.

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

Submitter Information

Submitter	BlueDop Medical Ltd.
Submitter Address	2 Leman Street, London, UK E1W 9US
Contact:	Jorge Millan, PhD
Telephone number	+1 786 416 5587
E-mail	jmillan@sigmabiomedical.com
Date prepared:	July 1, 2026

Device Name

Trade/Proprietary Name:	BlueDop Vascular Expert (BVE)
510(k)	K260700
Regulation Number:	21 CFR 870.2100
Regulation Name:	Cardiovascular Blood Flow Meter
Product Code:	DPW
Class	II
Panel	Circulatory System Device

Predicate Device

Predicate Device:	VascuChek Clinical Device
Sponsor	Remington Medical, Inc.
510(K)	K212065
Regulation Number:	21 CFR 870.2100
Regulation Name:	Cardiovascular Blood Flow Meter
Product Code:	DPW
Class	II
Panel	Circulatory System Device

Indications for Use:

The BlueDop Vascular Expert (BVE) is intended to non-invasively detect the presence of blood flow in peripheral arteries using Doppler ultrasound technology. The device provides Doppler waveform information to support clinical evaluation of peripheral vascular status.

The BVE is intended to be used as an adjunct to standard clinical assessment and does not provide a standalone diagnostic determination.

Device Description:

The BlueDop Vascular Expert (BVE) is a non-invasive, portable Doppler ultrasound system intended to detect the presence of blood flow in peripheral arteries using Doppler ultrasound technology. The system consists of a handheld ultrasound probe and a paired tablet computer. The probe transmits Doppler waveform data wirelessly to the tablet via Bluetooth for display and interpretation.

Conventional arm blood pressure cuff such as Summit Doppler ABI Vascular Cuff Package or other FDA-cleared equivalent (not included) are used to read the brachial blood pressure (BP) at Brachial, Posterior Tibial and Dorsalis Pedis levels bilaterally. The blood pressure readings are manually entered into the device. The probe incorporates diagnostic-level ultrasound emission and wireless communication capability. The tablet processes and displays the Doppler waveform and calculated parameters. The device is battery-powered and uses inductive wireless charging. The system does not deliver therapy and does not make autonomous diagnostic decisions.

Non-Clinical Data:

The following verification and validation testing were performed to support substantial equivalence:

- Electrical safety testing per IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2, including verification of essential performance under electromagnetic disturbance conditions
- Ultrasound acoustic output measurements in accordance with IEC 60601-2-37 and IEC 62127-1
- Doppler sensitivity measurements
- Doppler velocity measurement accuracy
- Temperature increase assessment
- Software verification and validation consistent with IEC 62304
- Cybersecurity verification
- Risk management per ISO 14971
- Biocompatibility evaluation of patient-contact materials
- Battery safety testing per IEC 62133-2:2017
- Cleaning and disinfection validation per ISO 17664-2:2021

The results of the non-clinical testing, including electrical safety, electromagnetic compatibility, ultrasound performance, software verification and validation, battery safety, cybersecurity, biocompatibility, and cleaning and disinfection validation, demonstrate that the BlueDop Vascular Expert meets all applicable safety and performance requirements and supports substantial equivalence to the predicate device.

Predicate Device

The BlueDop Vascular Expert is compared to the predicate VascuChek Clinical Device (K212065) because both devices have the same intended use and employ the same continuous-wave Doppler ultrasound technology.

Technical Characteristics Comparison:

The subject device has the same fundamental scientific technology and similar technological characteristics as the predicate device. The technological differences identified below were evaluated through appropriate verification and validation testing and demonstrated not to raise different questions of safety and effectiveness.

Feature Comparison:

The subject device has similar features and functionality to the predicate device, as summarized in the following comparison table.

Category	**Primary Predicate: VascuChek Clinical Device (K212065)**	**Subject: BlueDop Vascular Expert (BVE) (K260700)**	**Comparison**
Regulation / Classification	21 CFR 870.2100, DPW, Class II	21 CFR 870.2100, DPW, Class II	Same
Intended Use	Device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature.	The BlueDop Vascular Expert (BVE) is intended to non-invasively detect the presence of blood flow in peripheral arteries using Doppler ultrasound technology. The device provides Doppler waveform information to support clinical evaluation of peripheral vascular status. The BVE is intended to be used as an adjunct to standard clinical assessment and does not provide a standalone diagnostic determination.	Same
Prescription Status	Rx Only	Rx Only	Same
User Population	Qualified healthcare personnel	Qualified healthcare personnel	Same
Patient Population	Adults only	Adults, intact skin	Comparable intended patient population
Environment of Use	Hospitals, clinics	Hospitals, clinics	Same
Doppler Mode	Continuous-wave Doppler	Continuous-wave Doppler	Same
Operating Frequency	8 MHz	5 MHz	Comparable; no new risks

ISPTA.3 (mW/cm^2)	360	391	Comparable acoustic output intensity values within accepted diagnostic ultrasound exposure ranges
Principle of Operation	Continuous-wave ultrasonic Doppler	Continuous-wave ultrasonic Doppler	Same fundamental Doppler ultrasound principle of operation
Doppler Connectivity to Base	Wireless Probe	Wireless Probe	Same
ABI Workflow	None	Manual entry of clinician-obtained systolic pressures; ABI calculation	Different
Waveform Storage	None	Waveforms displayed/stored digitally/printed	Different
Numeric Outputs	None	ABI L/R	Different
Display	None	Tablet touchscreen	Different
Audio Output	Internal speaker	Digital audio tablet speaker	Same function
Connectivity	None	Bluetooth probe + Printer	Different
Data Storage	None	Numeric Patient ID, Printed record, Database encrypted at rest	Different
Power Source	Transceiver: Permanent two cell lithium iron secondary battery. Speaker Dock includes a permanent single cell lithium ion secondary battery and an external power source, A/C to D/C power supply.	Rechargeable tablet + probe	Similar
Applied Part Classification	IPX1	Type BF; IPX1	Similar
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	IEC 60601-1-2	IEC 60601-1-2	Same
Ultrasound Output	Within 60601-2-37	Within 60601-2-37	Same limits

Software	Embedded firmware	62304 Class B tablet app	Different
Cleaning	Wipe-only	Wipe-only	Same
Biocompatibility	Intact Skin	Intact Skin	Same
Sterility	Non-sterile	Non-sterile	Same

Evaluation of similarities and differences:

Similarities

The BlueDop Vascular Expert (BVE) is substantially equivalent to the predicate VascuChek Clinical Device (K212065) with respect to its intended use, technological characteristics, and fundamental scientific technology. Both devices are prescription-use, non-invasive continuous-wave (CW) Doppler ultrasound systems intended for use by qualified healthcare professionals to evaluate peripheral arterial blood flow in hospital and clinical environments. Both devices employ the same Doppler ultrasound principle of operation to detect blood flow and generate audible Doppler signals for vascular assessment. The devices are intended for use on adults with intact skin and comply with the same applicable medical electrical safety (IEC 60601-1), electromagnetic compatibility (IEC 60601-1-2), and diagnostic ultrasound output requirements (IEC 60601-2-37). The BVE has an acoustic output intensity comparable to that of the predicate and well within accepted diagnostic ultrasound exposure limits. In addition, both devices have comparable cleaning methods, are supplied non-sterile, are intended for repeated external use, and present the same overall risk profile associated with non-invasive Doppler vascular assessment.

Differences

The differences between the BlueDop Vascular Expert and the predicate device relate primarily to user interface, data management, and additional workflow functionality rather than to the fundamental technology used to detect blood flow. The BVE incorporates a tablet-based touchscreen interface, digital waveform display, electronic waveform storage, encrypted patient database, Bluetooth communication, and printing capability, whereas the predicate relies on a more limited hardware interface and does not provide digital waveform storage or integrated patient record management. These technological enhancements improve usability and documentation but do not alter the underlying Doppler measurement methodology or the intended clinical use.

The BVE also includes an Ankle-Brachial Index (ABI) calculation feature that allows the clinician to manually enter systolic blood pressure measurements obtained using standard clinical techniques and calculates the ABI value. The device does not automatically measure blood pressure or independently diagnose peripheral arterial disease; rather, it performs a mathematical calculation using clinician-acquired measurements to assist clinical assessment. This functionality serves as a workflow aid and does not introduce a new scientific technology or new intended use. The ABI calculation algorithm was verified and validated through software verification and validation testing to confirm the accurate implementation of the mathematical calculation using manually entered systolic blood pressure values. Testing demonstrated that the software performs the calculation as intended and does not introduce new questions of safety or effectiveness.

The BVE operates at a nominal Doppler frequency of 5 MHz compared with 8 MHz for the predicate device. Both frequencies are well established for peripheral vascular Doppler examinations and utilize the same continuous-wave Doppler technology. Performance testing, including Doppler sensitivity measurements, Doppler velocity measurement accuracy testing, and ultrasound acoustic output measurements, confirmed that operation at 5 MHz provides equivalent performance for the intended use and does not introduce new questions of safety or effectiveness. Similarly, differences in power supply architecture, software implementation, applied part classification, and system electronics reflect design evolution and modern implementation while remaining compliant with the same consensus safety standards applicable to diagnostic ultrasound devices.

The technological differences between the BlueDop Vascular Expert and the predicate device were evaluated through appropriate verification and validation testing, including electrical safety testing (IEC 60601-1), electromagnetic compatibility testing (IEC 60601-1-2), battery safety testing (IEC 62133-2:2017), ultrasound acoustic output measurements, Doppler sensitivity testing, Doppler velocity measurement accuracy testing, temperature rise assessment, software verification and validation, cybersecurity verification, risk management in accordance with ISO 14971, biocompatibility evaluation, and cleaning and disinfection validation (ISO 17664-2:2021).

Conclusion:

Non-clinical safety and performance testing, including electrical safety (IEC 60601-1), electromagnetic compatibility (IEC 60601-1-2), battery safety (IEC 62133-2:2017), ultrasound acoustic performance (IEC 60601-2-37), software verification and validation, cybersecurity, biocompatibility, and cleaning and disinfection validation (ISO 17664-2:2021), demonstrated that the BlueDop Vascular Expert met all predetermined acceptance criteria. The results demonstrate that the technological differences do not raise new questions of safety and effectiveness and that the BlueDop Vascular Expert performs as intended. Therefore, based on the intended use, technological characteristics, and results of the non-clinical performance testing, the BlueDop Vascular Expert is as safe and effective as the predicate device.