November 20, 2025

Remington Medical, Inc.
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy, Suite 120
Woodstock, Georgia 30188

Re: K251904
Trade/Device Name: VascuChek® Clinical and VascuChek® Surgical
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: June 20, 2025
Received: June 20, 2025

Dear Justin Gracyalny:

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); 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,

Stephen C. Browning -S

LCDR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251904

Device Name
VascuChek® Clinical and VascuChek® Surgical

Indications for Use *(Describe)*
VascuChek® Kit, VascuChek® Transceiver, VascuChek® Clinical Probe, VascuChek® Speaker Dock:
The VascuChek® device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature.

VascuChek® Kit, VascuChek® Transceiver, VascuChek® Surgical Probe, VascuChek® Speaker Dock:
The VascuChek® device is intended for the intraoperative and transcutaneous evaluation of blood flow in the following clinical applications:
- Intraoperative (Microvascular and Vascular)
- Intraoperative Neurological
- Transrectal and Peripheral Vascular.

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:
Remington Medical Inc.
VascuChek® Clinical and VascuChek® Surgical

Date Prepared	November 19, 2025
Sponsor	Remington Medical, Inc. 6830 Meadowridge Court Alpharetta, GA 30005 470-719-1084
510(k) Contact	Secure BioMed Evaluations Justin Gracyalny, MSE, RAC 7828 Hickory Flat Highway, Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	VascuChek® Clinical and VascuChek® Surgical
Common Name	Flowmeter, Blood, Cardiovascular
Classification Name	21 CFR §870.2100 Cardiovascular blood flowmeter Product Code: DPW
Device Class	II
Predicate Devices	K241583 Remington Medical, Inc. VascuChek Kit, VascuChek Transceiver, VascuChek Clinical Probe, VascuChek Charger (VC-KIT-01, VC-TRX-01, VC-CP-01, VC-CH-01); VascuChek Kit, VascuChek Transceiver, VascuChek Surgical Probe, VascuChek Charger (VC-KIT-01, VC-TRX-01, VC-SP-01, VC-CH-01)
Device Description	VascuChek® Surgical is a cardiovascular blood flowmeter comprised of three components: a sterile VascuChek® Surgical Probe with sheath which connects to the reusable, nonsterile VascuChek® Transceiver. The sheath is deployed over, and encapsulates the transceiver, allowing it to be used within the sterile field. The VascuChek® Transceiver is Bluetooth enabled and connects to the VascuChek® Speaker Dock. VascuChek® Clinical is a cardiovascular blood flowmeter comprised of three components: a non-sterile VascuChek® Clinical Probe which connects to the reusable, nonsterile VascuChek® Transceiver. The VascuChek® Transceiver is Bluetooth enabled and connects to the VascuChek® Speaker Dock. The VascuChek® device follows Track 1. A transmitter in the VascuChek® Transceiver drives the ultrasonic transmitting crystal located at the tip of the probe component. The ultrasonic waves generated by the sensor travel through the tissue just under the probe tip in a narrow beam. The reflected ultrasonic waves are received by the transducer and are converted via the piezoelectric effect into a high frequency electronic signal. The received electronic signal is amplified and

	detected. The result is a base band audio Doppler shifted signal which is filtered and converted to audio via a speaker.
Indications for Use Statement	VascuChek® Kit, VascuChek® Transceiver, VascuChek® Clinical Probe, VascuChek® Speaker Dock: The VascuChek® device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature. VascuChek® Kit, VascuChek® Transceiver, VascuChek® Surgical Probe, VascuChek® Speaker Dock: The VascuChek® device is intended for the intraoperative and transcutaneous evaluation of blood flow in the following clinical applications: - Intraoperative (Microvascular and Vascular) - Intraoperative Neurological - Transrectal and Peripheral Vascular.

Comparison of Technological Characteristics

The subject device is substantially equivalent to its predicate device (K241853 VascuChek® Kit, VascuChek® Transceiver, VascuChek® Clinical Probe, VascuChek® Charger (VC-KIT-01, VC-TRX-01, VC-CP-01, VC-CH-01); VascuChek® Kit, VascuChek® Transceiver, VascuChek® Surgical Probe, VascuChek® Charger (VC-KIT-01, VC-TRX-01, VC-SP-01, VC-CH-01)).

Similarities to Predicate

The subject device has the same intended use and technological characteristics as the identified predicate devices. The system employs identical technology as the identified predicate. The principles of operation and technological characteristics are identical to the predicate device. The system has similar or identical technological characteristics including:

- Identical patient population
- Identical intended use
- Identical principles of operation
- The subject and predicate device have the same components, including a surgical / clinical probe, transceiver with supporting firmware, and charger / speaker. The surgical / clinical probes are identical between the subject and predicate device.
- Both devices are provided as part of a kit with similar components. Both device kits include one (1) VascuChek® Transceiver connected to one (1) VascuChek® Probe Housing, one (1) VascuChek® Clinical Probe, one (1) VascuChek® Charger/Speaker Dock, and one (1) Aquasonic 100 Ultrasound Transmission Gel single-use packet (accessory), originally cleared under K827296.

Differences from Predicate

The primary differences between the subject and predicate device relate to hardware and firmware changes to support implementation of Bluetooth connectivity between the VascuChek® Transceiver and VascuChek® Speaker Dock. Specifically, in addition to acting as a charging station, the VascuChek® Speaker Dock also acts as a secondary wireless speaker option which was not a feature of the predicate device. Electrical safety and EMC testing per ANSI AAMI ES60601-1 and IEC 60601-1-2 respectively and software and cybersecurity testing per applicable FDA guidance were conducted to support these features.

The subject device VascuChek® Speaker Dock includes a rechargeable battery in addition to the AC to DC power supply. The predicate device charging station did not include a rechargeable battery. Electrical safety and EMC testing per ANSI AAMI ES60601-1 and IEC 60601-1-2 respectively and battery safety testing per IEC 62133-2 was conducted to support this difference.

The subject device operates at 418 mW/cm² while the predicate device operates at 462 mW/cm². Testing per IEC 60601-2-37 was conducted to support this change.

Non-Clinical Performance Testing Summary

All necessary testing has been performed to assure substantial equivalence to the predicate device and to demonstrate the subject device performs as intended. All testing was performed in accordance with relevant performance standards or internal test methods. The following evaluations were conducted:

- Electrical Safety Testing per ANSI AAMI ES60601-1
- EMC Testing per IEC 60601-1-2, IEC 60601-2-37
- Battery Safety Testing per IEC 62133-2
- Cleaning and Disinfection Validations per AAMI ST98, ASTM E1837
- Firmware Verification Testing
- Cybersecurity Penetration Testing
- Biocompatibility information was provided in accordance with Attachment G of the FDA guidance to support material differences

Descriptive software and cybersecurity information was also provided in accordance with FDA guidance documents “Content of Premarket Submissions for Device Software Functions” and “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions” respectively.

Conclusions

Based on the similarities of the intended use / indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate devices.