October 13, 2022

Remington Medical, Inc.
Matt Brown
VP of Quality and Regulatory Affairs
6830 Meadowridge Court
Alpharetta, Georgia 30005

Re: K211589
Trade/Device Name: VascuChek™
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular blood flowmeter
Regulatory Class: Class II
Product Code: DPW

Dear Matt Brown:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter cleared on January 27, 2022. Specifically, FDA is updating this SE Letter due to a typo in the clearance data, which was incorrectly dated as January 27, 2021.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact LCDR Stephen Browning, OHT2: Office of Cardiovascular Devices, 240-402-5241, stephen.browning@fda.hhs.gov.

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

January 27, 2021

Remington Medical, Inc.
Matt Brown
VP of Quality and Regulatory Affairs
6830 Meadowridge Court
Alpharetta, Georgia 30005

Re: K211589
Trade/Device Name: VascuChek ™
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: December 27, 2021
Received: December 28, 2021

Dear Matt Brown:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K211589

Device Name
VascuChek™

Indications for Use *(Describe)*

Remington Medical, Inc. 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.

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

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@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

Preparation Date	December 22, 2021
Applicant	Remington Medical, Inc. 6830 Meadowridge Court, Alpharetta, GA, USA 30005 Registration Number: 1056553 Owner/Operator Number: 9006473
Contact Person	C. Matt Brown, MS, CQE, RAC VP of Quality and Regulatory Affairs 470-719-1121 mattb@remmed.com
Trade Proprietary Name(s)	Remington Medical, Inc. VascuChek™
Common Name (s)	Flowmeter, Blood, Cardiovascular
Classification Name	21 CFR 870.2100 Cardiovascular blood flowmeter Product Code: DPW
Device Class:	II

Predicate Device:

Vascular Technology Incorporated (VTI) Surgical Doppler (K082870)

Description of the Device:

VascuChek™ is a cardiovascular blood flowmeter comprised of two 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™ device follows Track 1.

A transmitter in the 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. During the intervals when the unit is not transmitting, the device passes any reflected signals that it receives to a receiving circuit. This circuit amplifies the returning echoes, compares their frequency to that of the transmitted signal and converts any frequency differences into an audible tone.

Intended Use/Indications for Use

Remington Medical, Inc. 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 to Predicate Device:

The technological characteristics (design, specifications, materials, and performance) of the subject device and the predicate device are substantially equivalent.

		Subject Device: Remington Medical, Inc. VascuChek™		**Predicate Device: Vascular Technology Incorporated (VTI) Surgical Doppler (K082870)**	
Device Class FDA Product Code Regulation		Class II DPW 21 CFR 870.2100 (Flowmeter, Blood, Cardiovascular)		Class II DPW 21 CFR 870.2100 (Flowmeter, Blood, Cardiovascular)	
Intended Use		The Remington Medical, Inc. VascuChek™ is intended for the intraoperative and transcutaneous evaluation of blood flow.		The Vascular Technology Incorporated (VTI) Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow.	
Indications for Use Statement		Remington Medical, Inc. 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		The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow for the following clinical applications: • Intraoperative (Microvascular and Vascular), • Intraoperative Neurological • Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular	
Type of Use		Prescription Use		Prescription Use	
Use Environment		Hospital, Outpatient Surgery Center		Hospital, Outpatient Surgery Center	
Patient Population		Adults Only		Adults Only	
Installation and Use		Hand-Held (Transceiver and Probe)		Hand Held (Probe)	
Theory of Operation		Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.		Use of the Doppler effect to evaluate the flow velocity of blood in peripheral vasculature.	
Frequency		9 MHz		8 MHz and 20 MHz	
Global Maximum Outputs / Worst Case Setting	$I_{SPTA\ 3}$ (mW/cm^2)	359.7 mW/cm^2		< 94 mW/cm^2	
Mode of Operation		Ultrasonic Doppler/Continuous Wave		Ultrasonic Doppler/ Pulsed Wave	
Reusable		Probe	No, Single Use	Probe	No, Single Use
		Transceiver	Yes, Cleaning/Low Level Disinfection	Transceiver	Yes, Cleaning

Sterilization Method	Probe	ETO	Probe	ETO
Dimensions	221x 33 x 31 mm (8.7 in x 1.29 in x 1.22 in.)		6.5 in. D x 10 in. W x 4 in. H	
Weight	90 grams (0.198 lb)		2.6 lb, nom	
The degree of protection against harmful ingress of liquid (IPX rating)	Probe Transceiver Charger	1	Probe Transceiver	7 0
Power Supply	Rechargeable battery assembly with AC to DC Charger		Batteries or External Power Source (AC to DC)	
Battery Operating Voltage	6.4 VDC		12 VDC	
Battery Chemistry	1 - LiFePO4 rechargeable battery assembly		8 AA (LR6) alkaline batteries	
The degree of protection against electric shock	Probe	Type CF	Probe Transceiver	Type CF
Buttons	Three – Power, Volume Up, and Volume Down		Five – Power, Volume Up, Volume Down, Channel A, Channel B	
Status LED	One: Power and Battery Indicator		Six: Four indicate power on and volume, one indicates low batteries, one indicates active channel	
Calibration Required	No		No	
Maintenance	No		No	

Performance Data:

To demonstrate that the subject device, Remington Medical Inc. VascuChek™, is as safe and as effective as the predicate device, Vascular Technology Incorporated (VTI) Surgical Doppler, technological characteristics and performance criteria were evaluated. The following tests were performed on the subject device:

- Software/Firmware Performance
- Mechanical Performance
- Integrity of the Sterile Barrier
- Biocompatibility
- Pyrogenicity
- Shelf Life / Aging
- Device Lifecycle
- Sterility Assurance
- Reprocessing - Manual Cleaning and Intermediate-Level Disinfection
- Distribution Simulation
- Electrical Safety
- EMC
- Viral Permeability
- Environmental Performance Testing

In addition, the following in vivo tests were performed on the subject device and predicate device:

- Simulated Use – assess audio quality in measuring the velocity of blood flow at different vessel depths/sizes and compare performance of the new device to its predicate

The performance data (design, specifications, materials, and performance) of the Subject Device and the Predicate Device are substantially equivalent.

Clinical testing:

No clinical testing was required.

Conclusion:

The results of the non-clinical testing demonstrated that the subject device, Remington Medical Inc. VascuChek™, is substantially equivalent to the predicate device, Vascular Technology Incorporated (VTI) Surgical Doppler, with respect to intended use, design, materials, and technological characteristics.