



October 7, 2021

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

Re: K212065

Trade/Device Name: VascuChek Kit, VascuChek Transceiver, VascuChek Clinical Probe, VascuChek Charger

Regulation Number: 21 CFR 870.2100

Regulation Name: Cardiovascular Blood Flowmeter

Regulatory Class: Class II

Product Code: DPW

Dated: September 10, 2021

Received: September 13, 2021

Dear C. 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,

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

Indications for Use

510(k) Number (if known)
K212065

Device Name
VascuChek™ Clinical Device

Indications for Use (Describe)

The Remington Medical, Inc. VascuChek™ Clinical Device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature.

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.

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Traditional 510(k) Notification
Remington Medical Inc. VascuChek™ Clinical Device

Section 5 – 510(k) Summary

| | |
|----------------------------------|---|
| Preparation Date | July 1, 2021 – revised on September 8, 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™ Clinical Device |
| 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 nonsterile, single-use VascuChek™ Clinical Probe which connects to the reusable, nonsterile VascuChek™ Transceiver.

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

The Remington Medical, Inc. VascuChek™ Clinical Device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature.

Traditional 510(k) Notification
Remington Medical Inc. VascuChek™ Clinical Device

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™ Clinical Device | Predicate Device: Vascular Technology Incorporated (VTI) Surgical Doppler (K082870) |
|---|----------------------------------|--|---|
| Device Class | | Class II | Class II |
| FDA Product Code | | DPW | DPW |
| Regulation | | 21 CFR 870.2100 (Flowmeter, Blood, Cardiovascular) | 21 CFR 870.2100 (Flowmeter, Blood, Cardiovascular) |
| Intended Use | | The Remington Medical, Inc. VascuChek™ Clinical Device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature. | The Vascular Technology Incorporated (VTI) Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow. |
| Indications for Use Statement | | The Remington Medical, Inc. VascuChek™ Clinical Device is intended for the non-invasive transcutaneous evaluation of blood flow in Peripheral Vasculature. | The VTI Intraoperative Doppler Systems are intended for the intraoperative and transcutaneous evaluation of blood flow for the following clinical applications: <ul style="list-style-type: none"> • 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 | Vascular Patients |
| 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 | ISPTA 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 |
| | | Transceiver | Yes, Cleaning/Low Level Disinfection |
| Sterilization Method | | Not Applicable – Transceiver and Probe are nonsterile. | Probe ETO |

Traditional 510(k) Notification
Remington Medical Inc. VascuChek™ Clinical Device

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|---|---|---------|---|---------|
| 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 | 1 | Probe | 7 |
| | Transceiver | | Transceiver | 0 |
| | Charger | | | |
| 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 | Type CF |
| | | | Transceiver | |
| 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™ Clinical Device, 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
- Biocompatibility
- Device Lifecycle
- Reprocessing - Manual Cleaning and Low Level Disinfection
- Distribution Simulation
- Electrical Safety
- EMC
- Environmental Performance Testing

Traditional 510(k) Notification
Remington Medical Inc. VascuChek™ Clinical Device

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™ Clinical Device, is substantially equivalent to the predicate device, Vascular Technology Incorporated (VTI) Surgical Doppler, with respect to intended use, design, materials, and technological characteristics.