FDA 510(k) Premarket Notification

CLEARED

K241583 VascuChek Kit, VascuChek Transceiver, VascuChek Clinical Probe, VascuChek Charger (VC-KIT-01, VC-TRX-01, VC-CP-01, VC-CH-01)

Aug 30, 2024
88 days to decision

K241583 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k241583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Jun 3, 2024
Decision date	Aug 30, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VascuChek Kit, VascuChek Transceiver, VascuChek Surgical Probe, VascuChek Charger (VC-KIT-01, VC-TRX-01, VC-SP-01, VC-CH-01)

APPLICANT

Company	**Remington Medical, Inc.**
Location	Great Neck, NY, US
Contact	Dorothy Frieser
510(k) history	19 submissions · 19 cleared · 1993-2025

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Justin Gracyalny

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov