FDA 510(k) Premarket Notification

CLEARED

K212065 VascuChek Kit, VascuChek Transceiver, VascuChek Clinical Probe, VascuChek Charger

Oct 7, 2021
97 days to decision

K212065 · Product code: **DPW** · Cardiovascular
Source: https://www.510kdatabase.net/k212065/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Flowmeter, Blood, Cardiovascular (DPW)
Date received	Jul 2, 2021
Decision date	Oct 7, 2021
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k212065/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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