FDA 510(k) Premarket Notification

CLEARED

K233976 VasoGuard (V10, V8, V6, V4, V2)

Jul 19, 2024
217 days to decision

K233976 · Product code: **JOP** · Cardiovascular
Source: https://www.510kdatabase.net/k233976/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Ultrasonic (JOP)
Date received	Dec 15, 2023
Decision date	Jul 19, 2024
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Corvascular Diagnostics, LLC**
Location	Wayzata, MN, US
Contact	Spencer Lien
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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