FDA 510(k) Premarket Notification

K240119 VasQ

CLEARED

Feb 16, 2024
31 days to decision

K240119 · Product code: **QVQ** · Cardiovascular
Source: https://www.510kdatabase.net/k240119/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Extravascular Support For An Arteriovenous Fistula For Vascular Access (QVQ)
Date received	Jan 16, 2024
Decision date	Feb 16, 2024
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Laminate Medical Technologies , Ltd.**
Location	Tel Aviv, IL
Contact	Orit Yarden
510(k) history	2 submissions · 1 cleared · 2023-2024