FDA 510(k) Premarket Notification

K243918 Vasoview Hemopro 3 Power Supply

CLEARED

Feb 26, 2025
68 days to decision

K243918 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243918/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 20, 2024
Decision date	Feb 26, 2025
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Maquet Cardiovascular, LLC**
Location	San Jose, CA, US
Contact	Brad Sheals, MS
510(k) history	14 submissions · 14 cleared · 2008-2026