FDA 510(k) Premarket Notification

K252740 Voyant® Open Fusion Device (EB240/Open Fusion)

CLEARED

Nov 4, 2025
68 days to decision

K252740 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252740/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 28, 2025
Decision date	Nov 4, 2025
Days to decision	68 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Applied Medical Resources Corp.**
Location	Rancho Santa, CA, US
Contact	Derek Greene
510(k) history	45 submissions · 45 cleared · 2001-2025