FDA 510(k) Premarket Notification

K182653 Voyant Maryland Fusion Device

CLEARED

Nov 14, 2018
50 days to decision

K182653 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182653/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 25, 2018
Decision date	Nov 14, 2018
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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