FDA 510(k) Premarket Notification

K193292 Voyant 5mm Fusion Device, Voyant Maryland Fusion Device

CLEARED

Dec 20, 2019
23 days to decision

K193292 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193292/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 27, 2019
Decision date	Dec 20, 2019
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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