

K172624 Voyant 5mm Fusion DeviceFeb 13, 2018
165 days to decisionK172624 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k172624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 1, 2017
Decision date	Feb 13, 2018
Days to decision	165 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Resources Corporation
Location	Rancho Santa, CA, US
Contact	Andrew Nguyen
Website	https://www.appliedmedical.com/
510(k) history	12 submissions · 12 cleared · 2017-2026

Applied Medical Resources Corporation is a medical device manufacturer specializing in minimally invasive surgical instruments and access systems, with a manufacturing facility in Rancho Santa, California. The company develops a broad portfolio of surgical tools for general, plastic, and gynecological procedures. Applied Medical has received FDA 510(k) clearances from total submissions since 2017. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared portfolio. The most recent clearance was in 2026, demons...
