FDA 510(k) Premarket Notification

K162676 Voyant Open Fusion Device

CLEARED

Dec 1, 2016
66 days to decision

K162676 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2016
Decision date	Dec 1, 2016
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Applied Medical Resources**
Location	Launa Hills, CA, US
Contact	Jessica Cho
510(k) history	58 submissions · 58 cleared · 1992-2021