FDA 510(k) Premarket Notification

K231216 POTENZA

CLEARED

Dec 10, 2024
592 days to decision

K231216 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231216/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 28, 2023
Decision date	Dec 10, 2024
Days to decision	592 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jeisys Medical, Inc.**
Location	Littleton, CO, US
Contact	Bora Kim
510(k) history	15 submissions · 15 cleared · 2008-2024

REGULATORY CONSULTANT

Consulting firm	**E & M**
Contact	Sanghwa Myung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov