FDA 510(k) Premarket Notification

K242630 Aerin Console

CLEARED

Dec 10, 2024
98 days to decision

K242630 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242630/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 3, 2024
Decision date	Dec 10, 2024
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aerin Medical, Inc.**
Location	Sunnyvale, CA, US
Contact	Teri Feeley
510(k) history	9 submissions · 9 cleared · 2015-2024