FDA 510(k) Premarket Notification

CLEARED

K252083 HOTWIRE™ System RF Generator and Footswitch (optional accessory)

Aug 12, 2025
41 days to decision

K252083 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252083/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 2, 2025
Decision date	Aug 12, 2025
Days to decision	41 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Atraverse Medical, Inc.**
Location	Cardiff By The Sea, CA, US
Contact	Charles Yang
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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