FDA 510(k) Premarket Notification

K240932 HybridTherm System

CLEARED

Aug 5, 2024
122 days to decision

K240932 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 5, 2024
Decision date	Aug 5, 2024
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Erbe Elektromedizin GmbH**
Location	Orange, CA, US
Contact	Matthias Kollek
510(k) history	15 submissions · 15 cleared · 1994-2026