FDA 510(k) Premarket Notification

K183445 Erbe APCapplicators

CLEARED

Apr 4, 2019
113 days to decision

K183445 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k183445/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 12, 2018
Decision date	Apr 4, 2019
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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