FDA 510(k) Premarket Notification

K203150 Cool-tip RF Ablation System E Series

CLEARED

Feb 25, 2022
491 days to decision

K203150 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k203150/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 22, 2020
Decision date	Feb 25, 2022
Days to decision	491 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	Liron Bar Yaakov
510(k) history	88 submissions · 85 cleared · 2010-2026