

K203150 Cool-tip RF Ablation System E SeriesFeb 25, 2022
491 days to decisionK203150 · Product code: **GEI** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203150/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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