

K251813 CURIS II RF Generator (REF 360100-05)Feb 11, 2026
243 days to decisionK251813 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 13, 2025
Decision date	Feb 11, 2026
Days to decision	243 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sutter Medizintechnik GmbH
Location	Emmendingen, DE
Contact	Simone Peschl
510(k) history	9 submissions · 9 cleared · 2008-2026

REGULATORY CONSULTANT

Consulting firm	Visamed GmbH
Contact	Arne Briest

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

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