FDA 510(k) Premarket Notification

K251813 CURIS II RF Generator (REF 360100-05)

CLEARED

Feb 11, 2026
243 days to decision

K251813 · Product code: **GEI** · General & Plastic Surgery
Source: 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