

K251108 Erbe ESU Model VIO® 3n with AccessoriesAug 29, 2025
140 days to decisionK251108 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 11, 2025
Decision date	Aug 29, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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