

K243139 Reverso Pro SystemJan 22, 2025
114 days to decisionK243139 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 30, 2024
Decision date	Jan 22, 2025
Days to decision	114 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Indiba S. A. U.
Location	Sant Quirze Del Vall?s (Barcelona), ES
Contact	Amit Goren
510(k) history	3 submissions · 3 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	A. Stein Regulatory Affairs Consulting Company , Ltd.
Contact	Amit Goren

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243139/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026