FDA 510(k) Premarket Notification

K243139 Reverso Pro System

CLEARED

Jan 22, 2025
114 days to decision

K243139 · Product code: **GEI** · General & Plastic Surgery
Source: 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