

**K253918 Veineo System (00MEDRF4000TCUS 05CR45iT
06Pedal1St)**Jun 2, 2026
176 days to decisionK253918 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253918/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 8, 2025
Decision date	Jun 2, 2026
Days to decision	176 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	F Care Systems USA, LLC
Location	Miami, FL, US
Contact	Patrick Danciu
510(k) history	4 submissions · 4 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	F Care Systems NV
Contact	Steven Mertens

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/k253918/>; 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 June 9, 2026