

**K220725 HPR45i**Mar 20, 2023  
371 days to decisionK220725 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220725/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 14, 2022
Decision date	Mar 20, 2023
Days to decision	371 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>F Care Systems USA, LLC</b>
Location	Miami, FL, US
Contact	Patrick Danciu
510(k) history	3 submissions · 3 cleared · 2021-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Freyr, Inc.</b>
Contact	Shilpa Gampa

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220725/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026