FDA 510(k) Premarket Notification

K220725 HPR45i

CLEARED

Mar 20, 2023
371 days to decision

K220725 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k220725/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Freyr, Inc.**
Contact	Shilpa Gampa

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov