FDA 510(k) Premarket Notification

CLEARED

K252704 F Care RF System (00MEDRF4000US, 05RAFAELOPROBE, 05SPHERAPROBE, 06OUTPUTKAB, 06Pedal1St)

Nov 24, 2025
89 days to decision

K252704 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252704/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 27, 2025
Decision date	Nov 24, 2025
Days to decision	89 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	Danciu Patrick
510(k) history	3 submissions · 3 cleared · 2021-2025

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