

K210077 MED RF 4000Dec 17, 2021
339 days to decisionK210077 · Product code: **ONQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical Coagulation For Aesthetic (ONQ)
Date received	Jan 12, 2021
Decision date	Dec 17, 2021
Days to decision	339 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210077/> 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 May 26, 2026