FDA 510(k) Premarket Notification

K253917 ARION ARC System

CLEARED

Apr 10, 2026
123 days to decision

K253917 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k253917/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 8, 2025
Decision date	Apr 10, 2026
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Plasma Surgical, Inc.**
Location	Roswell, GA, US
Contact	Rupanshi Naik
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Pathmaker FDA Law, PLLC**
Contact	Amy Fowler

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