

K242227 GENE0 X ELITEOct 12, 2025
439 days to decisionK242227 · Product code: **PAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Jul 30, 2024
Decision date	Oct 12, 2025
Days to decision	439 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pollogen, Ltd.
Location	Binyamina, IL
Contact	Karen Smith
510(k) history	18 submissions · 18 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	The RC Insight Group, LLC
Contact	Lori Marzilli-Kahler

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

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