

K233766 Geneo X EliteMay 7, 2024
165 days to decisionK233766 · Product code: **PAY** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k233766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Nov 24, 2023
Decision date	May 7, 2024
Days to decision	165 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	A. Stein Regulatory Affairs Consulting Company , Ltd.
Contact	Amit Goren

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

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