

**K243217 Legend X Desktop System**Nov 1, 2024  
29 days to decisionK243217 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k243217/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 3, 2024
Decision date	Nov 1, 2024
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243217/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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