

K252576 Legend X Platform

Sep 12, 2025
29 days to decision

K252576 · Product code: **GEI** · Neurology
Source: <https://www.510kdatabase.net/k252576/>

SUBMISSION DETAILS

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Aug 14, 2025 |
| Decision date | Sep 12, 2025 |
| Days to decision | 29 days |
| Third-party review | Yes |
| 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

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|-----------------|--|
| Consulting firm | Regulatory Technology Services, LLC |
| Contact | Prithul Bom |

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