FDA 510(k) Premarket Notification

K243217 Legend X Desktop System

CLEARED

Nov 1, 2024
29 days to decision

K243217 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243217/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

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