FDA 510(k) Premarket Notification

K242241 Sunny

CLEARED

Mar 19, 2025
231 days to decision

K242241 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242241/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 31, 2024
Decision date	Mar 19, 2025
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**ShenB Co., Ltd.**
Location	Seongdong-Gu, KR
Contact	Sunny Kang
510(k) history	11 submissions · 11 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Hoy and Associates Regulatory Consulting**
Contact	Aubrey Thompson

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