FDA 510(k) Premarket Notification

K193070 VIVACE Electrosurgical Device

CLEARED

Apr 26, 2021
539 days to decision

K193070 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k193070/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 4, 2019
Decision date	Apr 26, 2021
Days to decision	539 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Aesthetics Biomedical**
Contact	Rachel Lord

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