

K193070 VIVACE Electrosurgical DeviceApr 26, 2021
539 days to decisionK193070 · Product code: **GEI** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193070/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 24, 2026