FDA 510(k) Premarket Notification

K252833 VIVA combo RF System

CLEARED

May 26, 2026
263 days to decision

K252833 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k252833/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 5, 2025
Decision date	May 26, 2026
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Starmed Co., Ltd.**
Location	Gyeonggi-Do, KR
Contact	Lee Honggeun
510(k) history	11 submissions · 11 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**MED Institute**
Contact	Daniel Dillon

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