

K253504 Volnewmer™

Jul 13, 2026
255 days to decision

K253504 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253504/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 31, 2025
Decision date	Jul 13, 2026
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Classys, Inc.
Location	Seoul, KR
Contact	Gene Choi
510(k) history	4 submissions · 4 cleared · 2023-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k253504/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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