

K240248 Volnewmer™Apr 29, 2024
90 days to decisionK240248 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240248/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 30, 2024
Decision date	Apr 29, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Classys, Inc.
Location	Seoul, KR
Contact	James Hoon Lim
510(k) history	3 submissions · 3 cleared · 2023-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240248/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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