FDA 510(k) Premarket Notification

# K240248 Volnewmer™

**CLEARED**

Apr 29, 2024
90 days to decision

K240248 · Product code: **GEI** · General & Plastic Surgery
Source: 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

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