FDA 510(k) Premarket Notification

# K251836 Dermatrix Duo

**CLEARED**

Feb 6, 2026
235 days to decision

K251836 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251836/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jun 16, 2025 |
| Decision date | Feb 6, 2026 |
| Days to decision | 235 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shenzhen Gsd Technology Co., Ltd.** |
| Location | Shenzhen, CN |
| Contact | Gordon Wang |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |