

K240897 CellinewNov 26, 2024
239 days to decisionK240897 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k240897/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Apr 1, 2024 |
| Decision date | Nov 26, 2024 |
| Days to decision | 239 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | VIOL Co., Ltd. |
| Location | Seongnam-Si, KR |
| Contact | Sugun Lee |
| 510(k) history | 5 submissions · 5 cleared · 2017-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240897/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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