

K253405 Prana SystemApr 1, 2026
183 days to decisionK253405 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253405/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Sep 30, 2025 |
| Decision date | Apr 1, 2026 |
| Days to decision | 183 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Prana Surgical |
| Location | Houston, TX, US |
| Contact | Carolyne Lu |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253405/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026