

**K260397 SYNERJET PRO (SP-1002)**Apr 6, 2026  
59 days to decisionK260397 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k260397/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Feb 6, 2026  |
| Decision date         | Apr 6, 2026  |
| Days to decision      | 59 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | InPhiuse (SP-1002); WOWJET (SP-1002)                       |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Hironic Co., Ltd.</b>              |
| Location       | Gyeonggi-Do, KR                       |
| Contact        | Byoungkook Kim                        |
| 510(k) history | 8 submissions · 8 cleared · 2018-2026 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260397/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026