

**K234140 VIVA combo RF System (VIVA combo RF System)**Jan 30, 2024  
32 days to decisionK234140 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k234140/>**SUBMISSION DETAILS**

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|                       |                                                            |
|-----------------------|------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Special                                                    |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Dec 29, 2023                                               |
| Decision date         | Jan 30, 2024                                               |
| Days to decision      | 32 days                                                    |
| Third-party review    | No                                                         |
| Combination product   | No                                                         |
| PCCP authorized       | No                                                         |
| Summary / Statement   | Summary                                                    |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Starmed Co., Ltd.</b>                |
| Location       | Gyeonggi-Do, KR                         |
| Contact        | Honggeun Lee                            |
| 510(k) history | 10 submissions · 10 cleared · 2017-2025 |

**REGULATORY CONSULTANT**

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|-----------------|------------------|
| Consulting firm | <b>JNM Korea</b> |
| Contact         | Bobae Jung       |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k234140/> 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