

**K243097 RM STAR EX with RMS Needle**Dec 26, 2024  
87 days to decisionK243097 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243097/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 30, 2024
Decision date	Dec 26, 2024
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Bomtech Electronics Co., Ltd.</b>
Location	Seoul, KR
Contact	Lee Junseok
510(k) history	2 submissions · 2 cleared · 2024-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Corazon</b>
Contact	Seo Juntaek

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/k243097/> 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 13, 2026