FDA 510(k) Premarket Notification

# K243097 RM STAR EX with RMS Needle

**CLEARED**

Dec 26, 2024
87 days to decision

K243097 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243097/

## SUBMISSION DETAILS

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|---|---|
| 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 | **Bomtech Electronics Co., Ltd.** |
| Location | Seoul, KR |
| Contact | Lee Junseok |
| 510(k) history | 2 submissions · 2 cleared · 2024-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Corazon** |
| Contact | Seo Juntaek |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov