

**K243143 E-PEN (E-PEN)**Apr 7, 2025  
189 days to decisionK243143 · Product code: **QAI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243143/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powered Microneedle Device (QAI)   |
| Date received         | Sep 30, 2024                       |
| Decision date         | Apr 7, 2025                        |
| Days to decision      | 189 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|----------------|
| 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

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243143/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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