

**K252211 Duoblade Plus SE (DB1EP, DB1EP-T, DB1EP-H, DB1EP-TH)**Aug 11, 2025  
27 days to decisionK252211 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k252211/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Special  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Jul 15, 2025   |
| Decision date         | Aug 11, 2025   |
| Days to decision      | 27 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | Duoblade Prime (DB1P, DB1P-T, DB1P-H, DB1P-TH)             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Cnc Technologies</b>               |
| Location       | Gwangmyeong-Si, KR                    |
| Contact        | Euna Choi                             |
| 510(k) history | 2 submissions · 2 cleared · 2023-2025 |

**REGULATORY CONSULTANT**

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|-----------------|----------------------|
| Consulting firm | <b>CTI Co., Ltd.</b> |
| Contact         | Jeong Mi Won         |

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

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