

**K183126 Electrosurgical accessory**May 8, 2019  
176 days to decisionK183126 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183126/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Nov 13, 2018   |
| Decision date         | May 8, 2019  |
| Days to decision      | 176 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>New Deantronics Taiwan , Ltd.</b>    |
| Location       | Tu Cheng City, TW                       |
| Contact        | Jane Liu                                |
| 510(k) history | 18 submissions · 18 cleared · 1998-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183126/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026