

**K973346 UNCOATED ELECTROSURGICAL ELECTRODE**Nov 7, 1997  
63 days to decisionK973346 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k973346/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Sep 5, 1997  |
| Decision date         | Nov 7, 1997  |
| Days to decision      | 63 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Megadyne Medical Products, Inc.</b>  |
| Location       | Murray, UT, US                          |
| Contact        | JOHN W SMITH                            |
| 510(k) history | 50 submissions · 48 cleared · 1990-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973346/> 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 14, 2026