

**K973159 ORATEC INTERVENTIONS MODEL ORA 40  
ELECTROTHERMAL GENERATOR**Sep 25, 1997  
34 days to decisionK973159 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k973159/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received         | Aug 22, 1997   |
| Decision date         | Sep 25, 1997   |
| Days to decision      | 34 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Oratec Interventions, Inc.</b>       |
| Location       | Mountain View, CA, US                   |
| Contact        | MICHAEL KWAN                            |
| 510(k) history | 24 submissions · 24 cleared · 1995-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973159/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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