

**K182434 LaparoGuard**Dec 13, 2018  
98 days to decisionK182434 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182434/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received         | Sep 6, 2018                                  |
| Decision date         | Dec 13, 2018                                 |
| Days to decision      | 98 days                                      |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mariner Endosurgery, Inc.</b>      |
| Location       | Hamilton, CA                          |
| Contact        | Mitch Wilson                          |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

**REGULATORY CONSULTANT**

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|-----------------|--|
| Consulting firm | <b>Ironstone Product Development, Inc.</b> |
| Contact         | Joel Ironstone                             |

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182434/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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