

**K161402 Bullfrog Micro-Infusion Device**Aug 18, 2016  
90 days to decisionK161402 · Product code: **KRA** · Cardiovascular  
Source: <https://www.510kdatabase.net/k161402/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Catheter, Continuous Flush (KRA)   |
| Date received         | May 20, 2016                       |
| Decision date         | Aug 18, 2016                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Mercator Medsystems, Inc.</b>      |
| Location       | San Leandro, CA, US                   |
| Contact        | Kirk P. Seward                        |
| 510(k) history | 5 submissions · 5 cleared · 2006-2021 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161402/> 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