

K153501 Bullfrog Micro-Infusion DeviceApr 15, 2016
130 days to decisionK153501 · Product code: **KRA** · Cardiovascular
Source: <https://www.510kdatabase.net/k153501/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Continuous Flush (KRA) |
| Date received | Dec 7, 2015 |
| Decision date | Apr 15, 2016 |
| Days to decision | 130 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mercator Medsystems, Inc. |
| Location | San Leandro, CA, US |
| Contact | KIRK P. SEWARD |
| 510(k) history | 5 submissions · 5 cleared · 2006-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153501/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026