

**K122506 SUREFIRE HIGH FLOW ANGIOGRAPHIC CATHETER,  
ACCESS**Sep 17, 2012  
31 days to decisionK122506 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122506/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Wire, Guide, Catheter (DQX)        |
| Date received         | Aug 17, 2012                       |
| Decision date         | Sep 17, 2012                       |
| Days to decision      | 31 days                            |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Surefire Medical, Inc.</b>           |
| Location       | Westminster, CO, US                     |
| Contact        | MARIO ARBESU                            |
| 510(k) history | 10 submissions · 10 cleared · 2011-2018 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122506/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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