

K160662 Surefire Infusion SystemMar 11, 2016
2 days to decisionK160662 · Product code: **DQO** · CardiovascularSource: <https://www.510kdatabase.net/k160662/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Mar 9, 2016
Decision date	Mar 11, 2016
Days to decision	2 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Surefire Medical, Inc.
Location	Westminster, CO, US
Contact	Lynne Aronson
510(k) history	10 submissions · 10 cleared · 2011-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160662/> 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 30, 2026