FDA 510(k) Premarket Notification

K160662 Surefire Infusion System

CLEARED

Mar 11, 2016
2 days to decision

K160662 · Product code: **DQO** · Cardiovascular
Source: 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