FDA 510(k) Premarket Notification

K140034 SUREFIRE GUIDING CATHETER

CLEARED

Feb 26, 2014
50 days to decision

K140034 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k140034/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jan 7, 2014
Decision date	Feb 26, 2014
Days to decision	50 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