

K151622 St.Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter, Livewire Electrophysiology Catheter, Response Electrophysiology Catheter with Lumen, Response Electrophysiology Catheter and SJM Epicardial Catheter System, Supreme Electrophysiology Catheter

Jul 15, 2015
29 days to decision

K151622 · Product code: DRF · Cardiovascular
Source: <https://www.510kdatabase.net/k151622/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Jun 16, 2015
Decision date	Jul 15, 2015
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St Jude Medical
Location	Minnetonka, MN, US
Contact	Maria Obreztkhikova
Website	http://www.sjm.com/
510(k) history	105 submissions · 105 cleared · 2000-2018

St Jude Medical was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St Jude Medical received FDA 510(k) clearances from total submissions between 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...