FDA 510(k) Premarket Notification

CLEARED

K160335 Advisor FL 15mm 12 Pole 333 Uni D, Advisor FL 20mm 12 Pole 555 Uni D, Advisor FL 15mm 12 Pole 333 Bi D, Advisor FL 20mm 12 Pole 555 Bi D

Dec 13, 2016
309 days to decision

K160335 · Product code: **DRF** · Cardiovascular
Source: https://www.510kdatabase.net/k160335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF)
Date received	Feb 8, 2016
Decision date	Dec 13, 2016
Days to decision	309 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St Jude Medical**
Location	Minnetonka, MN, US
Contact	Tamara Stanczak
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...