FDA 510(k) Premarket Notification

CLEARED

K121006 ENSITE ARRAY MULTI-ELECTRODE DIAGNOSTIC CATHETER

May 3, 2012
30 days to decision

K121006 · Product code: **MTD** · Cardiovascular
Source: https://www.510kdatabase.net/k121006/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Apr 3, 2012
Decision date	May 3, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St Jude Medical**
Location	Minnetonka, MN, US
Contact	NICOLE MARWICK
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...