

**K101968 SJM CONFIRM ICM, MODEL DRM2100, SJM CONFIRM PA, MODEL DM2100A**Sep 15, 2010  
65 days to decisionK101968 · Product code: **MXC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101968/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Jul 12, 2010
Decision date	Sep 15, 2010
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>St Jude Medical</b>
Location	Minnetonka, MN, US
Contact	SUSAN ENGELSON
Website	<a href="http://www.sjm.com/">http://www.sjm.com/</a>
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...

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