

**K212206 Jot Dx Insertable Cardiac Monitor**Aug 13, 2021  
29 days to decisionK212206 · Product code: **MXC** · CardiovascularSource: <https://www.510kdatabase.net/k212206/>**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 15, 2021
Decision date	Aug 13, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott (St. Jude Medical)</b>
Location	Sylmar, CA, US
Contact	Juni Sarkar
510(k) history	6 submissions · 6 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212206/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026