

**K190295 Confirm Rx Insertable Cardiac Monitor**Apr 10, 2019  
58 days to decisionK190295 · Product code: **MXC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190295/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Feb 11, 2019
Decision date	Apr 10, 2019
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott (St. Jude Medical)</b>
Location	Sylmar, CA, US
Contact	Laura Sparks
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/k190295/> 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 26, 2026