

K163407 Confirm Rx Insertable Cardiac Monitor (ICM) SystemSep 29, 2017
298 days to decisionK163407 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k163407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Dec 5, 2016
Decision date	Sep 29, 2017
Days to decision	298 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. Jude Medical, Inc.
Location	Salt Lake City, UT, US
Contact	Jennifer Dunham
Website	http://www.sjm.com/
510(k) history	23 submissions · 22 cleared · 1989-2018

St. Jude Medical, Inc. 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 1989 and 2018. The company specialized exclusively in Cardiovascular devices, establishing a focused portfolio in cardiac monitoring, catheter systems, and related interventional technologies. Founded in 1976 and publicly listed in 1977, St. Jude Medical achieved Fortune 500 status annually...

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