

K202888 Confirm Rx Insertable Cardiac MonitorNov 23, 2020
56 days to decisionK202888 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k202888/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Sep 28, 2020
Decision date	Nov 23, 2020
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott (St. Jude Medical)
Location	Sylmar, CA, US
Contact	Laura Sparks
510(k) history	6 submissions · 6 cleared · 2019-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202888/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026