

K193310 myMerlin Mobile Application (Android), myMerlin Mobile Application (iOS)Mar 17, 2020
109 days to decisionK193310 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k193310/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Nov 29, 2019
Decision date	Mar 17, 2020
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193310/> 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