

K122090 SJM CONFIRM IMPLANTABLE CARDIAC MONITORNov 15, 2012
122 days to decisionK122090 · Product code: **MXC** · Cardiovascular
Source: <https://www.510kdatabase.net/k122090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Recorder, Event, Implantable Cardiac, (without Arrhythmia Detection) (MXC)
Date received	Jul 16, 2012
Decision date	Nov 15, 2012
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. Jude Medical, Cardiac Rhythm Management Divisi
Location	Sylmar, CA, US
Contact	PLESSY PAUL
510(k) history	10 submissions · 10 cleared · 2008-2012

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