FDA 510(k) Premarket Notification

K172393 Advisor HD Grid Mapping Catheter, Sensor Enabled

CLEARED

Apr 23, 2018
258 days to decision

K172393 · Product code: **MTD** · Cardiovascular
Source: https://www.510kdatabase.net/k172393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Aug 8, 2017
Decision date	Apr 23, 2018
Days to decision	258 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St. Jude Medical, Inc.**
Location	Salt Lake City, UT, US
Contact	Jennifer Ruether
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...