FDA 510(k) Premarket Notification

K161171 PressureWire X Guidewire

CLEARED

Aug 15, 2016
111 days to decision

K161171 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k161171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Apr 26, 2016
Decision date	Aug 15, 2016
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St. Jude Medical, Inc.**
Location	Salt Lake City, UT, US
Contact	HUDA YUSUF
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...