FDA 510(k) Premarket Notification

CLEARED

K113584 PRESSUREWIRE CERTUS, CERTUS 300, AERIS, AERIS 300, AND RECEIVER

Mar 2, 2012
88 days to decision

K113584 · Product code: **DXO** · Cardiovascular
Source: https://www.510kdatabase.net/k113584/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Dec 5, 2011
Decision date	Mar 2, 2012
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St Jude Medical**
Location	Minnetonka, MN, US
Contact	BRYAN COWELL
Website	http://www.sjm.com/
510(k) history	105 submissions · 105 cleared · 2000-2018

St Jude Medical 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 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k113584/ 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 17, 2026