FDA 510(k) Premarket Notification

K073563 MODIFICATION TO PROXIS SYSTEM

CLEARED

Jan 31, 2008
43 days to decision

K073563 · Product code: **NFA** · Cardiovascular
Source: https://www.510kdatabase.net/k073563/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Temporary Coronary Saphenous Vein Bypass Graft For Embolic Protection (NFA)
Date received	Dec 19, 2007
Decision date	Jan 31, 2008
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**St Jude Medical**
Location	Minnetonka, MN, US
Contact	LINH PHAM
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...