FDA 510(k) Premarket Notification

K072278 BRK TRANSSEPTAL NEEDLE

CLEARED

Sep 13, 2007
28 days to decision

K072278 · Product code: **DRC** · Cardiovascular
Source: https://www.510kdatabase.net/k072278/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Aug 16, 2007
Decision date	Sep 13, 2007
Days to decision	28 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**St Jude Medical**
Location	Minnetonka, MN, US
Contact	Laura Moen-Ftacek
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...