

K181382 Guardian™ Burr Hole Cover SystemJul 20, 2018
56 days to decisionK181382 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k181382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Cover, Burr Hole (GXR)
Date received	May 25, 2018
Decision date	Jul 20, 2018
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St Jude Medical
Location	Minnetonka, MN, US
Contact	Rebecca Brunson
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...
