

K152342 Guardian Burr Hole Cover System, Guardian Screw, Burr Hole Cover

Jun 9, 2016
295 days to decisionK152342 · Product code: **GXR** · Neurology
Source: <https://www.510kdatabase.net/k152342/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Burr Hole (GXR)
Date received	Aug 19, 2015
Decision date	Jun 9, 2016
Days to decision	295 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St Jude Medical
Location	Minnetonka, MN, US
Contact	PARITA MEHTA
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...

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Device record: <https://www.510kdatabase.net/k152342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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