

**K110609 EPIDUCER LEAD DELIVERY SYSTEM**Jun 24, 2011  
113 days to decisionK110609 · Product code: **LHG** · Neurology  
Source: <https://www.510kdatabase.net/k110609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Spinal Epidural (LHG)
Date received	Mar 3, 2011
Decision date	Jun 24, 2011
Days to decision	113 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>St Jude Medical</b>
Location	Minnetonka, MN, US
Contact	RASHMI MOZA
Website	<a href="http://www.sjm.com/">http://www.sjm.com/</a>
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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