

**K112214 OCTRODEX(TM), QUATTRODEX(TM), INTRODEX(TM),  
EPIDURAL NEEDLE, STYLETS**Nov 17, 2011  
107 days to decisionK112214 · Product code: **GZB** · Neurology  
Source: <https://www.510kdatabase.net/k112214/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Spinal-cord, Implanted (pain Relief) (GZB)
Date received	Aug 2, 2011
Decision date	Nov 17, 2011
Days to decision	107 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>St. Jude Medical Neuromodulation</b>
Location	Plano, TX, US
Contact	PENNY HOUSTON
510(k) history	2 submissions · 2 cleared · 2011-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112214/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026