

**K110694 CONCORDE BULLET SPINAL SYSTEM**Oct 11, 2011  
211 days to decisionK110694 · Product code: **MAX** · Orthopedic  
Source: <https://www.510kdatabase.net/k110694/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Mar 14, 2011
Decision date	Oct 11, 2011
Days to decision	211 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Johnson &amp; Johnson</b>
Location	Raynham, MA, US
Contact	DAPHNEY GERMAIN-KOLAWOLE
Website	<a href="http://www.jnj.com">http://www.jnj.com</a>
510(k) history	9 submissions · 9 cleared · 2011-2012

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110694/> 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 May 18, 2026