

**K093637 JMS BLUNT A. V. FISTULA NEEDLE SET WITH SITE PREPARATION TOOL MODEL 820-5300, 820-6300 AND 820-7300**Feb 9, 2010  
77 days to decisionK093637 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k093637/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Nov 24, 2009
Decision date	Feb 9, 2010
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jms North America Corp.</b>
Location	Hayward, CA, US
Contact	E J SMITH
510(k) history	10 submissions · 10 cleared · 2003-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093637/>; 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 21, 2026