

**K112178 JMS APHERESIS NEEDLE SET WINGEATER(R) V2**Oct 27, 2011  
91 days to decisionK112178 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k112178/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Fistula (FIE)
Date received	Jul 28, 2011
Decision date	Oct 27, 2011
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>JMS North America Corporation</b>
Location	Crofton, MD, US
Contact	E.J. Smith
510(k) history	9 submissions · 9 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112178/> 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 26, 2026