

**K134019 MEDISYSTEMS ONESITE DUAL LUMEN NEEDLE WITH  
MASTERGUARD ANTI-STICK NEEDLE PROTECTOR,  
MEDISYSTEMS ONESITE DUAL LUMEN BUTTO**Sep 11, 2014  
255 days to decisionK134019 · Product code: FIE · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k134019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Dec 30, 2013
Decision date	Sep 11, 2014
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nxstage Medical, Inc.</b>
Location	Tewksburt, MA, US
Contact	LAURA F PLATH
510(k) history	51 submissions · 51 cleared · 2001-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k134019/>; 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 1, 2026