

**K161277 ConvertX Nephroureteral Stent System**Nov 22, 2016  
200 days to decisionK161277 · Product code: **FAD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k161277/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stent, Ureteral (FAD)
Date received	May 6, 2016
Decision date	Nov 22, 2016
Days to decision	200 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brightwater Medical</b>
Location	Dunlap, IL, US
Contact	BOB SMOUSE
510(k) history	2 submissions · 2 cleared · 2016-2019

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161277/> 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 28, 2026