

**K160417 Rezum System**Mar 17, 2016  
30 days to decisionK160417 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k160417/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Feb 16, 2016
Decision date	Mar 17, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nxthera, Inc.</b>
Location	Maple Grove, MN, US
Contact	J. Robert Paulson
510(k) history	3 submissions · 3 cleared · 2015-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160417/> 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 31, 2026