

**K150786 Rezum System**Aug 27, 2015  
155 days to decisionK150786 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k150786/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Mar 25, 2015
Decision date	Aug 27, 2015
Days to decision	155 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, JD
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/k150786/> 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