

K180237 Rezum SystemFeb 27, 2018
29 days to decisionK180237 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jan 29, 2018
Decision date	Feb 27, 2018
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nxthera, Inc.
Location	Maple Grove, MN, US
Contact	Kathy Simpson
510(k) history	3 submissions · 3 cleared · 2015-2018

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