

K191505 Rezum SystemAug 2, 2019
57 days to decisionK191505 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191505/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jun 6, 2019
Decision date	Aug 2, 2019
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nxthera (A Boston Scientific Company)
Location	Marborough, MA, US
Contact	Justin Kapitan
510(k) history	2 submissions · 2 cleared · 2019-2019

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