

K190093 Rezum Delivery Device, Rezum GeneratorMar 25, 2019
66 days to decisionK190093 · Product code: **KNS** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Jan 18, 2019
Decision date	Mar 25, 2019
Days to decision	66 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190093/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026