

**K223097 RenaNav Ureteroscope System**Jul 31, 2023  
304 days to decisionK223097 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k223097/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 30, 2022
Decision date	Jul 31, 2023
Days to decision	304 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CenterPoint Systems, LLC</b>
Location	West Valley City, UT, US
Contact	Marybeth Gamber
Website	<a href="https://centerpointsystems.com">https://centerpointsystems.com</a>
510(k) history	12 submissions · 12 cleared · 2021-2026

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