

**K243532 LumiRex Ureteroscope**Apr 28, 2025  
164 days to decisionK243532 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k243532/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Nov 15, 2024
Decision date	Apr 28, 2025
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Contra Healthcare Solutions, LLC</b>
Location	Butler, PA, US
Contact	John O'Conner
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243532/> 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 13, 2026