

**K253905 PrimeSight UltraView System**Apr 7, 2026  
123 days to decisionK253905 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k253905/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Dec 5, 2025
Decision date	Apr 7, 2026
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cogentix Medical, Inc.</b>
Location	Orangeburg, NY, US
Contact	Chanrasmey White
510(k) history	2 submissions · 2 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253905/> 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