

**K260013 CVAC Image Processor**Mar 6, 2026  
60 days to decisionK260013 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k260013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jan 5, 2026
Decision date	Mar 6, 2026
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Calyxo, Inc.</b>
Location	Pleasanton, CA, US
Contact	Joseph Catanese
Website	<a href="https://calyxoinc.com">https://calyxoinc.com</a>
510(k) history	3 submissions · 3 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260013/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026