

**K260965 CVAC Aspiration System**Apr 13, 2026  
21 days to decisionK260965 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k260965/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Mar 23, 2026
Decision date	Apr 13, 2026
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260965/> 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 14, 2026