

**K200419 Kalera Vacuum Aspiration Catheter (K-VAC)**May 22, 2020  
92 days to decisionK200419 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k200419/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Feb 20, 2020
Decision date	May 22, 2020
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kalera Medical, Inc.</b>
Location	San Diego, CA, US
Contact	Jee Shin
510(k) history	1 submissions · 1 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200419/> 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 June 28, 2026