

K250585 Lumena™ Ureteral Access SheathJun 27, 2025
120 days to decisionK250585 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250585/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Feb 27, 2025
Decision date	Jun 27, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cathegenix (Xiamen) Co., Ltd.
Location	Xiamen, CN
Contact	Deyuan Zheng
510(k) history	2 submissions · 1 cleared · 2025-2025

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