

K220065 Single Use Ureteral Access SheathMay 25, 2022
135 days to decisionK220065 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k220065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 10, 2022
Decision date	May 25, 2022
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Chuangxiang Medical Technology Co., Ltd.
Location	Hangzhou, CN
Contact	Lucius Long
510(k) history	13 submissions · 13 cleared · 2018-2026

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