

K203165 Disposable Ureteral Access SheathApr 30, 2021
189 days to decisionK203165 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k203165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Oct 23, 2020
Decision date	Apr 30, 2021
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Beyo Medical Technology Co., Ltd.
Location	Suzhou, CN
Contact	Aline Qin
510(k) history	1 submissions · 1 cleared · 2021-2021

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