

K253139 Disposable Distal CapMar 19, 2026
175 days to decisionK253139 · Product code: **FBN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Sep 25, 2025
Decision date	Mar 19, 2026
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mirco-Tech (Nanjing) Co., Ltd.
Location	Nanjing, CN
Contact	Sally He
510(k) history	4 submissions · 4 cleared · 2024-2026

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