

K253832 Dilation Balloon CatheterApr 24, 2026
144 days to decisionK253832 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k253832/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 1, 2025
Decision date	Apr 24, 2026
Days to decision	144 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253832/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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