

**K254153 Single-use Video Scope**Apr 3, 2026  
102 days to decisionK254153 · Product code: **FBN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k254153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Choledochoscope And Accessories, Flexible/rigid (FBN)
Date received	Dec 22, 2025
Decision date	Apr 3, 2026
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PB Digital Controller

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254153/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026