

**K151671 Disposable Multistage Dilation Balloon Catheter**Oct 16, 2015  
116 days to decisionK151671 · Product code: **FGE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k151671/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jun 22, 2015
Decision date	Oct 16, 2015
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micro-Tech (Nanjing) Co., Ltd.</b>
Location	Nanjing, CN
Contact	BECK LI
Website	<a href="https://www.micro-tech.com.cn">https://www.micro-tech.com.cn</a>
510(k) history	41 submissions · 41 cleared · 2015-2026

Micro-Tech (Nanjing) Co., Ltd. is a medical device manufacturer based in Nanjing, China. Founded in 2000, the company specializes in minimally invasive medical devices for clinical diagnosis and treatment. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. 83% of submissions focus on Gastroenterology & Urology devices, including tissue resection systems, closure devices, stents, and endoscopic accessories. The company's regulatory activity spans from 2015 to 2026, with recent clearances demonstrating continued inno...

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