

**K211021 Sterile Biliary Stone Retrieval Balloon Catheter,
Retrieval Balloon / short-wire compatible**May 6, 2022
396 days to decisionK211021 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Apr 5, 2021
Decision date	May 6, 2022
Days to decision	396 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Micro-Tech (Nanjing) Co., Ltd.
Location	Nanjing, CN
Contact	Cecilia Sun
Website	https://www.micro-tech.com.cn
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...