

K230127 Biliary Plastic Stent, Biliary Plastic Stent Introducer, Biliary Plastic Stent Set, Biliary Plastic Stent Introducer/ short-wire compatible, Biliary Plastic Stent Set/ short-wire compatible

Sep 6, 2023
232 days to decision

K230127 · Product code: **FGE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230127/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jan 17, 2023
Decision date	Sep 6, 2023
Days to decision	232 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	Sally He
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...