FDA 510(k) Premarket Notification

CLEARED

K252492 Visualized Access and Delivery Catheter

Apr 24, 2026
259 days to decision

K252492 · Product code: **SHU** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Date received	Aug 8, 2025
Decision date	Apr 24, 2026
Days to decision	259 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PB Digital Controller

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...

REGULATORY CONSULTANT

Consulting firm	**Mirco-Tech (Nanjing) Co., Ltd.**
Contact	Sally He

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov