FDA 510(k) Premarket Notification

K251692 Advanced Tissue Resection Device

CLEARED

Feb 21, 2026
264 days to decision

K251692 · Product code: **FDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Snare, Flexible (FDI)
Date received	Jun 2, 2025
Decision date	Feb 21, 2026
Days to decision	264 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 Hu
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