FDA 510(k) Premarket Notification

K250229 Dual Action Tissue Closure Device

CLEARED

Sep 8, 2025
224 days to decision

K250229 · Product code: **PKL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k250229/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Jan 27, 2025
Decision date	Sep 8, 2025
Days to decision	224 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...