

K180325 Single Use MultiClip DeviceJun 1, 2018
116 days to decisionK180325 · Product code: **PKL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Metal Clip For The Gi Tract (PKL)
Date received	Feb 5, 2018
Decision date	Jun 1, 2018
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Micro-Tech (Nanjing) Co., Ltd.
Location	Nanjing, CN
Contact	Becky Li
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...
