

**K193601 Single Use Electrosurgical Knife**Jul 24, 2020  
214 days to decisionK193601 · Product code: **GEI** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k193601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 23, 2019
Decision date	Jul 24, 2020
Days to decision	214 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Micro-Tech (Nanjing) Co., Ltd.</b>
Location	Nanjing, CN
Contact	Sally He
Website	<a href="https://www.micro-tech.com.cn">https://www.micro-tech.com.cn</a>
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...