

K190030 Embrella Endoscopic Distal AttachmentMar 5, 2019
57 days to decisionK190030 · Product code: **FED** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k190030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Access Overtube, Gastroenterology-urology (FED)
Date received	Jan 7, 2019
Decision date	Mar 5, 2019
Days to decision	57 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	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...