

K213060 Areus™ Endobronchial Ultrasound Aspiration Needle, Trident™ Endobronchial Ultrasound Aspiration NeedleJul 20, 2022
301 days to decisionK213060 · Product code: KTI · Anesthesiology
Source: <https://www.510kdatabase.net/k213060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	Sep 22, 2021
Decision date	Jul 20, 2022
Days to decision	301 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...