

K212852 Areus(TM) Adapt Endoscopic Ultrasound Aspiration Needle, Trident(TM) Endoscopic Ultrasound Aspiration NeedleDec 6, 2021
90 days to decisionK212852 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k212852/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Ultrasound System, Gastroenterology-urology (ODG) |
| Date received | Sep 7, 2021 |
| Decision date | Dec 6, 2021 |
| Days to decision | 90 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 | Cecilia Sun |
| 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...