

K221784 Single-use Video Pancreaticobiliary Scope, PB Digital Controller

Feb 16, 2023
240 days to decisionK221784 · Product code: **FBN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221784/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Choledochoscope And Accessories, Flexible/rigid (FBN) |
| Date received | Jun 21, 2022 |
| Decision date | Feb 16, 2023 |
| Days to decision | 240 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...