

K220210 Disposable Endoscopy Adapter SetJun 17, 2022
142 days to decisionK220210 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k220210/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscope Channel Accessory (ODC) |
| Date received | Jan 26, 2022 |
| Decision date | Jun 17, 2022 |
| Days to decision | 142 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------------------------------|
| Company | Yangzhou Fartley Medical Instrument Technology Co., Ltd. |
| Location | Yangzhou, CN |
| Contact | Tina Han |
| 510(k) history | 7 submissions · 7 cleared · 2022-2025 |

REGULATORY CONSULTANT

| | |
|-----------------|------------------------------------------------|
| Consulting firm | Shanghai Thinkwell Consulting Co., Ltd. |
| Contact | Ethan Liu |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220210/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026