

K250695 Single-use Ureteral Access SheathJul 8, 2025
123 days to decisionK250695 · Product code: **FED** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250695/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Access Overtube, Gastroenterology-urology (FED) |
| Date received | Mar 7, 2025 |
| Decision date | Jul 8, 2025 |
| Days to decision | 123 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shenzhen HugeMed Medical Technical Development Co., Ltd. |
| Location | Shenzhen, CN |
| Contact | Cathy Shi |
| 510(k) history | 7 submissions · 7 cleared · 2023-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250695/> 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 13, 2026