

K192258 Disposable Valve SetsDec 30, 2019
132 days to decisionK192258 · Product code: **ODC** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k192258/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscope Channel Accessory (ODC) |
| Date received | Aug 20, 2019 |
| Decision date | Dec 30, 2019 |
| Days to decision | 132 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Zhejiang Chuangxiang Medical Technology Co., Ltd. |
| Location | Hangzhou, CN |
| Contact | Lucius Long |
| 510(k) history | 13 submissions · 13 cleared · 2018-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192258/> 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 June 28, 2026