

K233284 Vial Adapter with FilterMay 1, 2024
215 days to decisionK233284 · Product code: LHI · General Hospital
Source: <https://www.510kdatabase.net/k233284/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, I.v. Fluid Transfer (LHI) |
| Date received | Sep 29, 2023 |
| Decision date | May 1, 2024 |
| Days to decision | 215 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Hangzhou Qiantang Longyue Biotechnology Co., Ltd. |
| Location | Hangzhou, CN |
| Contact | Chunyu Wang |
| 510(k) history | 4 submissions · 4 cleared · 2023-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai Lingfu Technology Co., Ltd. |
| Contact | Esther Zhang |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233284/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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