

K242898 Sterilization Pouches and ReelsFeb 21, 2025
151 days to decisionK242898 · Product code: **FRG** · General Hospital
Source: <https://www.510kdatabase.net/k242898/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wrap, Sterilization (FRG) |
| Date received | Sep 23, 2024 |
| Decision date | Feb 21, 2025 |
| Days to decision | 151 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Shanghai Jianzhong Medical Packaging Co., Ltd. |
| Location | Shanghai, CN |
| Contact | Xinhua Wei |
| 510(k) history | 3 submissions · 3 cleared · 2007-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242898/> 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 14, 2026