

K211728 Sterile hypodermic syringes for single useOct 5, 2021
123 days to decisionK211728 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k211728/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Jun 4, 2021 |
| Decision date | Oct 5, 2021 |
| Days to decision | 123 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Jiangsu Kangyou Medical Instrument Co., Ltd. |
| Location | Jintan, CN |
| Contact | Xiang Yao |
| 510(k) history | 1 submissions · 1 cleared · 2021-2021 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211728/> 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 26, 2026