

K231729 Sterile syringes for single use with/without needleSep 8, 2023
87 days to decisionK231729 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k231729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 13, 2023
Decision date	Sep 8, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wepon Medical Technology Co., Ltd.
Location	Wenling, CN
Contact	Di Zhao
510(k) history	5 submissions · 5 cleared · 2022-2023

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](https://accessdata.fda.gov)

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231729/> 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