

K212033 Disposable Sterile Syringe, with/without needleAug 17, 2022
414 days to decisionK212033 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k212033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 29, 2021
Decision date	Aug 17, 2022
Days to decision	414 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	luer/luer-lock, Disposable insulin syringe, Disposable Hypodermic needle

APPLICANT

Company	Shandong Zhushi Pharmaceutical Group Co., Ltd.
Location	Heze, CN
Contact	Junhui Zhu
510(k) history	8 submissions · 8 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Humiss Lnc.
Contact	Bruce Cai

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/k212033/> 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