

K212226 DR Safety Syringe, Sterile Hypodermic needle for Single useSep 29, 2021
75 days to decisionK212226 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k212226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Jul 16, 2021
Decision date	Sep 29, 2021
Days to decision	75 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhuhai DR Medical Instruments Co., Ltd.
Location	Zhuhai, CN
Contact	Xu Jianhai
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k212226/> 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