

K211484 Disposable Sterile Syringe with Safety NeedleMar 1, 2022
293 days to decisionK211484 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k211484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	May 12, 2021
Decision date	Mar 1, 2022
Days to decision	293 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Disposable Sterile Syringe with Needle; Disposable Sterile Syringe; Disposable Safety Needles

APPLICANT

Company	Shinva Ande Healthcare Apparatus Co., Ltd.
Location	Zibo, CN
Contact	Xiaolei Tian
510(k) history	6 submissions · 6 cleared · 2017-2022

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
Contact	Olivia Meng

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/k211484/> 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