

K220057 Disposable Sterile Syringe with permanently attached needleOct 7, 2022
274 days to decisionK220057 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k220057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Jan 6, 2022
Decision date	Oct 7, 2022
Days to decision	274 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Auto-disable Syringe for Fixed-dose Immunization

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220057/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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