

K231165 Shina SyringeOct 27, 2023
185 days to decisionK231165 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k231165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Apr 25, 2023
Decision date	Oct 27, 2023
Days to decision	185 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Shina Safety Syringe

APPLICANT

Company	Shina Med Corporation
Location	Anseong-Si, KR
Contact	Tae Joo Ha
510(k) history	7 submissions · 7 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	Plusglobal
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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