

**K192679 Sterile Syringe with Safety needle for Single Use,
Sterile Syringe for Single Use, Sterile Safety Needle for Single
Use**Apr 10, 2020
197 days to decisionK192679 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k192679/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Sep 26, 2019
Decision date	Apr 10, 2020
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gentier Medical (Shanghai), Inc.
Location	Shanghai, CN
Contact	Lenny Cao
510(k) history	5 submissions · 5 cleared · 2017-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192679/>; 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 27, 2026