

**K212652 Sterile Syringe with Fixed Safety Needle for Single Use**Mar 2, 2022  
191 days to decisionK212652 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k212652/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Aug 23, 2021
Decision date	Mar 2, 2022
Days to decision	191 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212652/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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