

K211329 Sterile Disposable Syringe with Saftey Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Syringe, Sterile Disposable Safety Needle, Sterile Disposable NeedleNov 15, 2021
196 days to decisionK211329 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k211329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	May 3, 2021
Decision date	Nov 15, 2021
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Kangbao Medical Equipment Co., Ltd.
Location	Yangzhou, CN
Contact	Rujun Tang
510(k) history	5 submissions · 5 cleared · 2018-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

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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