

K221247 Sterile Disposable Syringe with Safety Needle, Sterile Disposable Syringe with Needle, Sterile Disposable Safety Needle, Sterile Disposable Needle

Nov 1, 2022
183 days to decision

K221247 · Product code: **MEG** · General Hospital
Source: <https://www.510kdatabase.net/k221247/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	May 2, 2022
Decision date	Nov 1, 2022
Days to decision	183 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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Device record: <https://www.510kdatabase.net/k221247/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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