

K213158 Syringe with permanently attached needleJul 21, 2022
296 days to decisionK213158 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k213158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 28, 2021
Decision date	Jul 21, 2022
Days to decision	296 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Berpu Medical Technology Co., Ltd.
Location	Wenzhou, CN
Contact	David Yu
510(k) history	9 submissions · 9 cleared · 2016-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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