FDA 510(k) Premarket Notification

K223678 Sterile Syringes for Single Use

CLEARED

Feb 9, 2023
63 days to decision

K223678 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k223678/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 8, 2022
Decision date	Feb 9, 2023
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shanghai Kindly Enterprise Development Group Co., Ltd.**
Location	Shanghai, CN
Contact	Amy Li
510(k) history	2 submissions · 2 cleared · 2023-2023