FDA 510(k) Premarket Notification

K231729 Sterile syringes for single use with/without needle

CLEARED

Sep 8, 2023
87 days to decision

K231729 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k231729/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 13, 2023
Decision date	Sep 8, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wepon Medical Technology Co., Ltd.**
Location	Wenling, CN
Contact	Di Zhao
510(k) history	5 submissions · 5 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Shanghai Lingfu Technology Co., Ltd.**
Contact	Esther Zhang

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