FDA 510(k) Premarket Notification

CLEARED

K212920 Sterile Safety Syringe with Needle for Single Use, Sterile Safety Hypodermic Needle for Single Use,Sterile Auto-Disable Syringe with Needle for Single Use

Mar 11, 2022
178 days to decision

K212920 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k212920/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 14, 2021
Decision date	Mar 11, 2022
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shandong Weigao Group Medical Polymer Co., Ltd.**
Location	Shanghai, CN
Contact	Lina Liu
510(k) history	7 submissions · 7 cleared · 2007-2023

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