FDA 510(k) Premarket Notification

K221080 Sterile Safety Hypodermic Needles for Single Use

CLEARED

Oct 4, 2022
175 days to decision

K221080 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k221080/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 12, 2022
Decision date	Oct 4, 2022
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Sichuan Prius Biotechnology Co., Ltd.**
Location	Yibin, CN
Contact	Yan Liu
510(k) history	9 submissions · 9 cleared · 2021-2022

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