FDA 510(k) Premarket Notification

CLEARED

K214075 Safety Blood Collection / Infusion Set (with/without needle holder), Blood Collection / Infusion Set (with/without needle holder)

Apr 12, 2022
106 days to decision

K214075 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k214075/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 27, 2021
Decision date	Apr 12, 2022
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.**
Location	Taihu, Anqing City, CN
Contact	Bingyi Xiang
510(k) history	12 submissions · 12 cleared · 2019-2024

REGULATORY CONSULTANT

Consulting firm	**Irc**
Contact	Charles Mack

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