FDA 510(k) Premarket Notification

K211293 Safety Winged Blood Collection Sets

CLEARED

Jun 25, 2021
60 days to decision

K211293 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k211293/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Apr 26, 2021
Decision date	Jun 25, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Promisemed Hangzhou Meditech Co., Ltd.**
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	**Medtech Review, LLC**
Contact	John Beasley

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