FDA 510(k) Premarket Notification

K220900 Safety Blood Collection Needles with/without Needle Holder

CLEARED

Aug 10, 2022
135 days to decision

K220900 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k220900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Mar 28, 2022
Decision date	Aug 10, 2022
Days to decision	135 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	**Shanghai Mind-Link Consulting Co., Ltd.**
Contact	Evan Hu

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