

K212019 Blood Collection Needle for Single Use & Blood Collection Needle with Holder for Single Use, Safety Blood Collection Needle for Single Use, Safety Blood Collection Needle with Holder for Single Use, Blood Collection Set for Single Use & Safety Blood Collection Set with Holder for Single Use, Safety Blood Collection Set for Single Use & Blood Collection Set with Holder for Single

Nov 4, 2021
129 days to decision

K212019 · Product code: JKA · General Hospital
Source: <https://www.510kdatabase.net/k212019/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Jun 28, 2021
Decision date	Nov 4, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Micsafe Medical Technology Co., Ltd.
Location	Yancheng, CN
Contact	Tony Yang
510(k) history	5 submissions · 5 cleared · 2018-2021

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k212019/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026