

**K200027 Blood Collection Needle with/without Holder, Safety
Blood Collection Needle with/without Holder, Luer Access
Device-holder with Preattached Multiple Sample Adapter**Sep 9, 2020
247 days to decisionK200027 · Product code: **JKA** · General Hospital
Source: <https://www.510kdatabase.net/k200027/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Jan 6, 2020
Decision date	Sep 9, 2020
Days to decision	247 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangsu Caina Medical Co.,Ltd
Location	Jiangyin, CN
Contact	Jianwei Pan
510(k) history	21 submissions · 21 cleared · 2018-2024

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](https://accessdata.fda.gov)

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