FDA 510(k) Premarket Notification

**CLEARED**

# K230080 Blood Collection Set, Blood Collection Set with Holder, Safety Blood Collection Set, Safety Blood Collection Set with Holder, Blood

Jul 7, 2023
177 days to decision

K230080 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k230080/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA) |
| Date received | Jan 11, 2023 |
| Decision date | Jul 7, 2023 |
| Days to decision | 177 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Yangzhou Medline Industry, Co., Ltd.** |
| Location | Yangzhou, CN |
| Contact | Hu Tingting |
| 510(k) history | 2 submissions · 2 cleared · 2017-2023 |

## 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

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230080/ 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 27, 2026