

K211293 Safety Winged Blood Collection SetsJun 25, 2021
60 days to decisionK211293 · Product code: **FMI** · General HospitalSource: <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 | Promised Hangzhou Meditech Co., Ltd. |
| Location | Hangzhou, CN |
| Contact | Zearou Yang |
| 510(k) history | 34 submissions · 34 cleared · 2017-2026 |

REGULATORY CONSULTANT

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|-----------------|----------------------------|
| 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211293/> 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 13, 2026