

K230061 Insulin SyringeNov 30, 2023
325 days to decisionK230061 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k230061/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Syringe, Piston (FMF) |
| Date received | Jan 9, 2023 |
| Decision date | Nov 30, 2023 |
| Days to decision | 325 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

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|-----------------|--|
| 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230061/> 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 14, 2026