

**K230043 Insulin Pen Needle**Sep 20, 2023  
257 days to decisionK230043 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k230043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 6, 2023
Decision date	Sep 20, 2023
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.</b>
Location	Taihu, Anqing City, CN
Contact	Bingyi Xiang
510(k) history	12 submissions · 12 cleared · 2019-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230043/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026