

**K202319 Insulin Pen Needle (Ordinary Type), Insulin Pen Needle (Safety Type)**Nov 12, 2021  
452 days to decisionK202319 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k202319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 17, 2020
Decision date	Nov 12, 2021
Days to decision	452 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tianjin Huahong Technology Co., Ltd.</b>
Location	Tianjin, CN
Contact	Yan Li
510(k) history	11 submissions · 11 cleared · 2021-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202319/> 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 24, 2026