

**K220603 Disposable Medical Safety Hypodermic Needle**Aug 23, 2022  
174 days to decisionK220603 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k220603/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 2, 2022
Decision date	Aug 23, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hantech Medical Device Co., Ltd.</b>
Location	Ningbo, CN
Contact	Arnold YANG
510(k) history	5 submissions · 5 cleared · 2022-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220603/> 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 26, 2026