

**K210232 Sterile Hypodermic Needles for Single Use**Sep 23, 2021  
238 days to decisionK210232 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k210232/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 28, 2021
Decision date	Sep 23, 2021
Days to decision	238 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhejiang Kangkang Medical-Devices Co., Ltd.</b>
Location	Yuhuan, CN
Contact	Chun Guo
510(k) history	4 submissions · 4 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210232/> 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