

K213535 Sterile Safety Hypodermic Needles for Single UseMay 13, 2022
189 days to decisionK213535 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k213535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Nov 5, 2021
Decision date	May 13, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213535/> 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 26, 2026