

**K191643 TK Sterile Hypodermic Needle**Dec 19, 2019  
183 days to decisionK191643 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k191643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 19, 2019
Decision date	Dec 19, 2019
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Anhui Tiangkang Medical Technology Co., Ltd.</b>
Location	Tianchang, CN
Contact	Bai Baodong
510(k) history	12 submissions · 12 cleared · 2019-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191643/> 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 25, 2026