

**K210864 Safety Pen Needle**Feb 17, 2022  
331 days to decisionK210864 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k210864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 23, 2021
Decision date	Feb 17, 2022
Days to decision	331 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sandstone Medical (Suzhou), Inc.</b>
Location	Suzhou, CN
Contact	Juanjuan Sun
510(k) history	3 submissions · 3 cleared · 2021-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Grace Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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