

**K230635 Pen Needle**Jun 2, 2023  
87 days to decisionK230635 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k230635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 7, 2023
Decision date	Jun 2, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Caina Medical Co.,Ltd</b>
Location	Jiangyin, CN
Contact	Camel Zhou
510(k) history	21 submissions · 21 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230635/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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