

K222739 Disposable Insulin Pen NeedleApr 6, 2023
209 days to decisionK222739 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k222739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 9, 2022
Decision date	Apr 6, 2023
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hantech Medical Device Co., Ltd.
Location	Ningbo, CN
Contact	Rachel Jin
510(k) history	5 submissions · 5 cleared · 2022-2023

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