

K252908 Easydrip Classic Pen NeedleMar 25, 2026
194 days to decisionK252908 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k252908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 12, 2025
Decision date	Mar 25, 2026
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Easydrip Plus Pen Needle; Easydrip Classic Pro Pen Needle; Easydrip Plus Pro Pen Needle

APPLICANT

Company	Sandstone Medical (Suzhou), Inc.
Location	Suzhou, CN
Contact	Susan Sun
510(k) history	3 submissions · 3 cleared · 2021-2026

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