

K193422 Easydrip Pen Needle, Easydrip Plus Pen NeedleFeb 2, 2021
421 days to decisionK193422 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k193422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Dec 9, 2019
Decision date	Feb 2, 2021
Days to decision	421 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Elly Xu

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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