

**K253112 Sofjec (Single use Needle)**May 21, 2026  
239 days to decisionK253112 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k253112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Sep 24, 2025
Decision date	May 21, 2026
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Sofjec (Single use Syringe with or without Needle); Sofjec (Membrane Filter Syringe)

**APPLICANT**

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Company	<b>Hlb Lifescience Co., Ltd.</b>
Location	Anseong, KR
Contact	Jiwon Han
510(k) history	2 submissions · 2 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mediguide, Inc.</b>
Contact	Yongjun Lee

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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