

**K241856 Sofjec (Single use Needle)**Dec 23, 2024  
179 days to decisionK241856 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k241856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Jun 27, 2024
Decision date	Dec 23, 2024
Days to decision	179 days
Third-party review	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	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241856/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026