

**K212635 Sofjec**Feb 13, 2023  
543 days to decisionK212635 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k212635/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Aug 19, 2021
Decision date	Feb 13, 2023
Days to decision	543 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hwajin Medical Co., Ltd.</b>
Location	Cheonan-Si, KR
Contact	Jeon Sung Hun
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212635/> 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 27, 2026