

**K210848 Sure-Fine Insulin Syringes**Mar 1, 2022  
344 days to decisionK210848 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k210848/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Mar 22, 2021
Decision date	Mar 1, 2022
Days to decision	344 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shina Med Corporation</b>
Location	Anseong-Si, KR
Contact	Jeong Ho Ryu
510(k) history	7 submissions · 7 cleared · 2016-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>LK Consulting Group USA, Inc.</b>
Contact	Priscilla Chung

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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