

**K191531 Sure-Fine Insulin Syringes**Sep 6, 2019  
88 days to decisionK191531 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k191531/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Jun 10, 2019
Decision date	Sep 6, 2019
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191531/> 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 25, 2026