

# K210216 Disposable Automatically Retractable Insulin Safety Syringe

Mar 4, 2022  
401 days to decisionK210216 · Product code: **MEG** · General Hospital  
Source: <https://www.510kdatabase.net/k210216/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Jan 27, 2021
Decision date	Mar 4, 2022
Days to decision	401 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shantou Wealy Medical Instrument Co.,Ltd</b>
Location	Echo, OR, US
Contact	Yuhe Yang
510(k) history	6 submissions · 6 cleared · 2012-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Sungo Management Consulting Company Limited.</b>
Contact	Raymond Luo

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210216/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026