

**K231856 TopFine® LDS (Low Dead Space) Syringe (2 models  
(TS-LDS2334, TS-LDS2534))**Mar 15, 2024  
266 days to decisionK231856 · Product code: **QNQ** · General Hospital  
Source: <https://www.510kdatabase.net/k231856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNG)
Date received	Jun 23, 2023
Decision date	Mar 15, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medexel Co.,Ltd</b>
Location	Anseong-Si, KR
Contact	Juntaek Seo
510(k) history	3 submissions · 3 cleared · 2016-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Plusglobal</b>
Contact	Peter Chung

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/k231856/> 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 14, 2026