

**K213013 Sterile Single-use LDV Syringe, CHOICARE Sterile Single-use LDV Syringe**Sep 19, 2022  
364 days to decisionK213013 · Product code: **QNG** · General Hospital  
Source: <https://www.510kdatabase.net/k213013/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNG)
Date received	Sep 20, 2021
Decision date	Sep 19, 2022
Days to decision	364 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jeil Tech Co., Ltd.</b>
Location	Sejong-Si, KR
Contact	Chun-Gi Lee
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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

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/k213013/> 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