

**K210748 Well-life TM Pen Needles, Well-life TM Safety Pen Needles**May 25, 2022  
439 days to decisionK210748 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k210748/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Mar 12, 2021
Decision date	May 25, 2022
Days to decision	439 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>W. L. Med Co., Ltd.</b>
Location	Anseong-Si, KR
Contact	Ha Tae Joo
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

---

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/k210748/> 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 27, 2026