FDA 510(k) Premarket Notification

CLEARED

K210748 Well-life TM Pen Needles, Well-life TM Safety Pen Needles

May 25, 2022
439 days to decision

K210748 · 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	**W. L. Med Co., Ltd.**
Location	Anseong-Si, KR
Contact	Ha Tae Joo
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Plusglobal**
Contact	Peter Chung

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov