

K213010 FEELject LDV (Low dead volume) syringeMay 31, 2023
618 days to decisionK213010 · Product code: **QNG** · General Hospital
Source: <https://www.510kdatabase.net/k213010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNG)
Date received	Sep 20, 2021
Decision date	May 31, 2023
Days to decision	618 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Feeltech Co., Ltd.
Location	Gunsan-Si, KR
Contact	Kim Geun Sik
510(k) history	4 submissions · 4 cleared · 2018-2025

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213010/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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