

K250127 TSK SyringeJul 30, 2025
194 days to decisionK250127 · Product code: **QNG** · General Hospital
Source: <https://www.510kdatabase.net/k250127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Low Dead Space Piston Syringe (QNG)
Date received	Jan 17, 2025
Decision date	Jul 30, 2025
Days to decision	194 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tsk Laboratory, Japan
Location	Tochigi-Ken, JP
Contact	Yumi Ueda
510(k) history	3 submissions · 3 cleared · 1997-2025

REGULATORY CONSULTANT

Consulting firm	Namsa
Contact	Anna Galea

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