

K260754 Fastep COVID-19 Antigen Pen Home TestJun 5, 2026
88 days to decisionK260754 · Product code: **QYT** · Microbiology
Source: <https://www.510kdatabase.net/k260754/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Covid-19 Antigen Test (QYT)
Date received	Mar 9, 2026
Decision date	Jun 5, 2026
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Fastep COVID-19 Antigen Pen Test

APPLICANT

Company	Assure Tech., LLC
Location	Wilmington, DE, US
Contact	Allen Chen
510(k) history	6 submissions · 6 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	LSI International, Inc.
Contact	Jenny Xia

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.netDevice record: <https://www.510kdatabase.net/k260754/> Data sourced from FDA 510(k) public records (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. - Generated June 13, 2026