

K252243 Fastplex™ BCR-ABL (p210) %IS digital PCR Kit

Jul 2, 2026
349 days to decision

K252243 · Product code: OYX · Medical Genetics
Source: <https://www.510kdatabase.net/k252243/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bcr/abl1 Monitoring Test (OYX)
Date received	Jul 18, 2025
Decision date	Jul 2, 2026
Days to decision	349 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Precigenome, Ltd. Co;
Location	Suzhou, CN
Contact	Yaqi Wang
510(k) history	1 submissions · 1 cleared · 2026-2026