

K221869 BCR-ABL1 (p210) % IS Kit (Digital PCR Method)Sep 5, 2023
434 days to decisionK221869 · Product code: **OYX** · Medical GeneticsSource: <https://www.510kdatabase.net/k221869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bcr/abl1 Monitoring Test (OYX)
Date received	Jun 28, 2022
Decision date	Sep 5, 2023
Days to decision	434 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Sniper Medical Technologies Co., Ltd.
Location	Suzhou, CN
Contact	Peng Zhang
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Sinow Medical AS
Contact	Huifang Zhao

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

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