

K212878 Sample preservation solutionApr 8, 2024
942 days to decisionK212878 · Product code: **QBD** · Microbiology
Source: <https://www.510kdatabase.net/k212878/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	Sep 9, 2021
Decision date	Apr 8, 2024
Days to decision	942 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhejiang Gene Science Co., Ltd.
Location	Shaoxing, CN
Contact	Zhang Feng
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Guangzhou Osmunda Medical Device Technical Services Co., Ltd.
Contact	Olivia Meng

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/k212878/> 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 May 13, 2026