

K231013 DNA/RNA Shield SafeCollect Saliva Collection kitSep 28, 2023
171 days to decisionK231013 · Product code: **QBD** · Microbiology
Source: <https://www.510kdatabase.net/k231013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	Apr 10, 2023
Decision date	Sep 28, 2023
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zymo Research
Location	Irvine, CA, US
Contact	Julie Ogi
Website	http://www.zymoresearch.com
510(k) history	2 submissions · 2 cleared · 2020-2023

Zymo Research is a biomedical products and services company with a manufacturing facility in Irvine, California. The company specializes in molecular biology solutions, including sample collection, nucleic acid purification, and next-generation sequencing services. Founded over 30 years ago, Zymo Research serves research, diagnostic, and clinical markets globally. The company has received FDA 510(k) clearances from total submissions, with all submissions focused on Microbiology devices. Clearances span from 2020 to 2023. Notable cleared devices include specimen collection...