

K202641 DNA/RNA Shield Collection TubeDec 14, 2020
94 days to decisionK202641 · Product code: **QBD** · Microbiology
Source: <https://www.510kdatabase.net/k202641/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	Sep 11, 2020
Decision date	Dec 14, 2020
Days to decision	94 days
Third-party review	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...
