

K212113 MagXtract Collection TubeJul 28, 2022
386 days to decisionK212113 · Product code: **QBD** · Microbiology
Source: <https://www.510kdatabase.net/k212113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Microbial Nucleic Acid Storage And Stabilization Device (QBD)
Date received	Jul 7, 2021
Decision date	Jul 28, 2022
Days to decision	386 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Magbio Genomics, Inc.
Location	Gaithersburg, MD, US
Contact	Mothomang Mlalazi-Oyinloye
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Brij Strategic Consultations, LLC
Contact	Mukesh Kumar

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

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