

K240279 VIDAS TBI (GFAP, UCH-L1)May 1, 2024
90 days to decisionK240279 · Product code: **QAT** · Immunology
Source: <https://www.510kdatabase.net/k240279/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Trauma Assessment Test (QAT)
Date received	Feb 1, 2024
Decision date	May 1, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	Chris Goodpaster
510(k) history	251 submissions · 250 cleared · 1983-2026

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