

K233184 T2Bacteria® PanelFeb 8, 2024
133 days to decisionK233184 · Product code: **QBX** · Microbiology
Source: <https://www.510kdatabase.net/k233184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Direct Blood Bacterial Nucleic Acid Detection System (QBX)
Date received	Sep 28, 2023
Decision date	Feb 8, 2024
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	T2biosystems, Inc.
Location	Lexington, MA, US
Contact	Rachel Gilbert
Website	http://www.t2biosystems.com/
510(k) history	6 submissions · 5 cleared · 2014-2024

T2 Biosystems, Inc. was an in vitro diagnostics company formerly based in Lexington, Massachusetts. The company is no longer operating and has completed winding down of operations. During its active period, T2 Biosystems received FDA 510(k) clearances from total submissions. The company specialized exclusively in Microbiology devices, with its first clearance in 2014 and most recent clearance in 2024. This regulatory track record reflects the company's focus on rapid diagnostic solutions for infectious disease detection. For inquiries regarding T2 Biosystems's cleared devi...