FDA 510(k) Premarket Notification

K231336 T2 Biothreat Panel

CLEARED

Sep 15, 2023
130 days to decision

K231336 · Product code: **QVR** · Microbiology
Source: https://www.510kdatabase.net/k231336/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiplex Nucleic Acid Detection System For Biothreat Agents (QVR)
Date received	May 8, 2023
Decision date	Sep 15, 2023
Days to decision	130 days
Third-party review	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' cleared devi...