FDA 510(k) Premarket Notification

K234063 T2Candida 1.1 Panel

CLEARED

Sep 13, 2024
266 days to decision

K234063 · Product code: **PII** · Microbiology
Source: https://www.510kdatabase.net/k234063/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Candida Species Nucleic Acid Detection System (PII)
Date received	Dec 22, 2023
Decision date	Sep 13, 2024
Days to decision	266 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' cleared devi...