

K173536 T2Candida 1.1 PanelDec 12, 2017
27 days to decisionK173536 · Product code: **PII** · Microbiology
Source: <https://www.510kdatabase.net/k173536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Candida Species Nucleic Acid Detection System (PII)
Date received	Nov 15, 2017
Decision date	Dec 12, 2017
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	T2biosystems, Inc.
Location	Lexington, MA, US
Contact	Anne Marie Whalen
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...
