FDA 510(k) Premarket Notification

K243499 NG-Test® CTX-M MULTI

CLEARED

Jun 4, 2025
204 days to decision

K243499 · Product code: **PTJ** · Microbiology
Source: https://www.510kdatabase.net/k243499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Phenotypic Test Kit, Non-susceptible/elevated Mic Organisms, Cultured Isolates (PTJ)
Date received	Nov 12, 2024
Decision date	Jun 4, 2025
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ng Biotech**
Location	Guipry, FR
Contact	Milovan Stankov-Puges
Website	https://www.ngbiotech.com/
510(k) history	2 submissions · 2 cleared · 2019-2025

Ng Biotech develops and manufactures rapid diagnostic tests for infectious disease detection. Founded in 2012 by pioneers in the rapid test industry, the company operates from Guipry, France with two 5,000 m² industrial facilities. The company specializes in point-of-care diagnostics using a proprietary immunoassay platform, delivering results in minutes from minimal sample volumes. Ng Biotech has received FDA 510(k) clearances from total submissions since 2019. The company's regulatory portfolio focuses exclusively on Microbiology devices, with recent cleared products ta...

REGULATORY CONSULTANT

Consulting firm	**Hardy Diagnostics**
Contact	Anna Klavins

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov