

K200533 binx io CT/NG Assay and binx io CT/NG SystemApr 27, 2020
56 days to decisionK200533 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k200533/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Mar 2, 2020
Decision date	Apr 27, 2020
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Binx Health, Inc.
Location	Boston, MA, US
Contact	Sarah Kalil
510(k) history	2 submissions · 2 cleared · 2019-2020

CLINICAL EVIDENCE - NCT03071510

Evaluation of the Atlas Genetics io® CTNG System

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	7128 patients (actual)
Study sites	10 sites
Condition studied	Chlamydia Trachomatis; Gonorrhea
Study type	Observational
Completion date	Aug 30, 2019
Sponsor	Binx Health Limited (Industry)

Primary outcome

Diagnostic Accuracy compared to positive Composite Infected Status from comparator devices

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03071510510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine). 510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026