

K191352 binx health io CT/NG AssayAug 8, 2019
80 days to decisionK191352 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k191352/>**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	May 20, 2019
Decision date	Aug 8, 2019
Days to decision	80 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/NCT03071510

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