

K193081 Rheonix STI TriPlex Assay, Rheonix EncompassMDx Workstation (instrument and software), Rheonix Urine Specimen Collection KitDec 17, 2021
773 days to decisionK193081 · Product code: **QEP** · Microbiology
Source: <https://www.510kdatabase.net/k193081/>**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	Nov 5, 2019
Decision date	Dec 17, 2021
Days to decision	773 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rheonix, Inc.
Location	Ithaca, NY, US
Contact	Richard Montagna
510(k) history	1 submissions · 1 cleared · 2021-2021

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