

**K230267 NeuMoDx CT/NG Assay 2.0**Dec 22, 2023  
325 days to decisionK230267 · Product code: **QEP** · Microbiology  
Source: <https://www.510kdatabase.net/k230267/>**SUBMISSION DETAILS**

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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	Jan 31, 2023
Decision date	Dec 22, 2023
Days to decision	325 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neumodx Molecular, Inc.</b>
Location	Ann Arbor, MI, US
Contact	Eveline Arnold
510(k) history	2 submissions · 2 cleared · 2018-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qiagen</b>
Contact	Eveline Arnold

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

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