

K220026 Genomadix Cube CYP2C19 SystemMar 21, 2023
440 days to decisionK220026 · Product code: **NTI** · Toxicology
Source: <https://www.510kdatabase.net/k220026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Jan 5, 2022
Decision date	Mar 21, 2023
Days to decision	440 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Genomadix, Inc.
Location	Kanata (Ottawa), CA
Contact	Amanda Dwyer
510(k) history	1 submissions · 1 cleared · 2023-2023

CLINICAL EVIDENCE - NCT04473573**Spartan Cube CYP2C19 Inter Laboratory Reproducibility Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	8 patients (actual)
Study sites	3 sites
Condition studied	Genotyping Techniques
Primary purpose	Screening
Study type	Interventional
Study design	Single group
Masking	Double blind
Completion date	Mar 17, 2020
Sponsor	Spartan Bioscience Inc. (Industry)

Primary outcome

% Agreement of test results generated on the Spartan Cube CYP2C19 System and bidirectional sequencing

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04473573510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220026/> Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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