

K250050 miDiagnostics HSV-1&2 CSF TestSep 30, 2025
263 days to decisionK250050 · Product code: **PGH** · Microbiology
Source: <https://www.510kdatabase.net/k250050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hsv-1 And Hsv-2 Cns Nucleic-acid Based Panel (PGH)
Date received	Jan 10, 2025
Decision date	Sep 30, 2025
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Midiagnostics NV
Location	Leuven, BE
Contact	Katrin Martens
510(k) history	1 submissions · 1 cleared · 2025-2025

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