

**K230944 MeMed BV**Jun 30, 2023  
87 days to decisionK230944 · Product code: **QPS** · Microbiology  
Source: <https://www.510kdatabase.net/k230944/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay For Host Biomarkers Of Infection (QPS)
Date received	Apr 4, 2023
Decision date	Jun 30, 2023
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MeMed Diagnostics, Ltd.</b>
Location	Tirat Carmel, IL
Contact	Efrat Hartog-David
510(k) history	3 submissions · 3 cleared · 2021-2023

**CLINICAL EVIDENCE - NCT05439551**

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**Evaluating the Analytical Equivalency of Serum and Whole Blood Samples Run on the MeMed Key® Platform (Perseverance Study)**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	215 patients (actual)
Study sites	5 sites
Condition studied	Acute Infection
Study type	Observational
Completion date	Sep 29, 2023
Sponsor	MeMed Diagnostics Ltd. (Industry)

**Primary outcome**

Measuring the MeMed BV® score with whole blood and serum samples from patients suspected of acute bacterial or viral infection and demonstrating the equivalence between the two matrices.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05439551](https://clinicaltrials.gov/study/NCT05439551)