

K240045 QStat CartridgeMar 27, 2024
82 days to decisionK240045 · Product code: **QFR** · Hematology
Source: <https://www.510kdatabase.net/k240045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Jan 5, 2024
Decision date	Mar 27, 2024
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hemosonics, LLC
Location	Charlottesville, VA, US
Contact	Deborah Winegar
510(k) history	8 submissions · 7 cleared · 2019-2025

CLINICAL EVIDENCE - NCT06025708

Quantra QStat Sample Type Comparison

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	25 patients (actual)
Study sites	1 site
Condition studied	Coagulation Defect; Bleeding
Study type	Observational
Completion date	Mar 1, 2024
Sponsor	HemoSonics LLC (Industry)

Primary outcome**Comparison of QStat Clot time (CT) in arterial and venous samples**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06025708

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240045/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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