

K251404 Quantra QStat CartridgeAug 25, 2025
111 days to decisionK251404 · Product code: **QFR** · Hematology
Source: <https://www.510kdatabase.net/k251404/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	May 6, 2025
Decision date	Aug 25, 2025
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251404/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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