

**K213917 QStat Cartridge**Nov 29, 2022  
349 days to decisionK213917 · Product code: **QFR** · Hematology  
Source: <https://www.510kdatabase.net/k213917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Dec 15, 2021
Decision date	Nov 29, 2022
Days to decision	349 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemosonics, LLC</b>
Location	Charlottesville, VA, US
Contact	Iskra Mrakovic
510(k) history	8 submissions · 7 cleared · 2019-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213917/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026