

**K201513 Quantra QPlus System**Aug 21, 2020  
74 days to decisionK201513 · Product code: **QFR** · Hematology  
Source: <https://www.510kdatabase.net/k201513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Jun 8, 2020
Decision date	Aug 21, 2020
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemosonics, LLC</b>
Location	Charlottesville, VA, US
Contact	Anne Zavertrnik
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/k201513/> 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