

**K230461 Quantra Hemostasis Analyzer**Mar 24, 2023  
31 days to decisionK230461 · Product code: **QFR** · Hematology  
Source: <https://www.510kdatabase.net/k230461/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Feb 21, 2023
Decision date	Mar 24, 2023
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230461/> 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