

K223433 Quantra QPlus SystemDec 13, 2022
29 days to decisionK223433 · Product code: **QFR** · Hematology
Source: <https://www.510kdatabase.net/k223433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Nov 14, 2022
Decision date	Dec 13, 2022
Days to decision	29 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223433/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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