

K232215 Quantra Hemostasis AnalyzerAug 24, 2023
29 days to decisionK232215 · Product code: **QFR** · Hematology
Source: <https://www.510kdatabase.net/k232215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties (QFR)
Date received	Jul 26, 2023
Decision date	Aug 24, 2023
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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