



August 25, 2025

HemoSonics LLC  
Garrett Sparks  
Manager, Regulatory Affairs  
4020 Stirrup Creek Drive  
Suite 105  
Durham, North Carolina 27703

Re: K251404

Trade/Device Name: Quantra QStat Cartridge

Regulation Number: 21 CFR 864.5430

Regulation Name: Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties  
In Perioperative Patients

Regulatory Class: Class II

Product Code: QFR

Dated: May 6, 2025

Received: July 24, 2025

Dear Garrett Sparks:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory->

[assistance/contact-us-division-industry-and-consumer-education-dice](#)) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Takeesha Taylor-bell -S**

Takeesha Taylor-Bell  
Deputy Director  
Division of Immunology and Hematology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K251404

Device Name

QStat Cartridge

Indications for Use (Describe)

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous or arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.

The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma, liver transplantation, and peripartum obstetric procedures.

Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.

For prescription use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## **510(K) SUMMARY**

### **APPLICANT INFORMATION**

*Date prepared:* 21 August 2025

*Submission Date:* May 2025

*Submitter Information:* HemoSonics, LLC  
4020 Stirrup Creek Drive, Suite 105  
Durham, NC 27703  
Phone: 919-599-7325

*Contact Person:* Garrett Sparks  
Email: [gsparks@hemosonics.com](mailto:gsparks@hemosonics.com)  
Phone: 919-599-7325

### **PROPRIETARY AND ESTABLISHED NAMES**

QStat® Cartridge

### **REGULATORY INFORMATION**

*Trade/Device Name:* QStat Cartridge

*Regulation Number:* 21 CFR 864.5430

*Regulation Name:* Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients

*Regulatory Classification:* Class II

*Product Code:* QFR

### **PURPOSE OF SUBMISSION**

To extend the intended use and indications for use statement for the QStat Cartridge to peripartum obstetric patients. This change does not alter the device's fundamental scientific technology.

### **MEASURAND**

The combination of clot time and clot stiffness parameters measured from the four channels of the cartridge provides information about the functional role of coagulation factors, fibrinogen, clot lysis, and platelets in the sample.

### **TYPE OF TEST**

The QStat Cartridge is an in vitro diagnostic device used with the Quantra Hemostasis Analyzer to assess a patient's coagulation system by measuring the viscoelastic properties of a blood sample during clot formation and clot lysis. The QStat Cartridge is used with the Quantra Hemostasis Analyzer (instrument) and QStat Controls (external Quality Control materials).

## **INTENDED USE AND INDICATIONS FOR USE STATEMENT**

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous or arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.

The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma, liver transplantation, and peripartum obstetric procedures.

Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.

For prescription use only.

## **DEVICE DESCRIPTION**

The QStat Cartridge is a single-use, multi-channel disposable plastic cartridge used with the Quantra Hemostasis Analyzer for the evaluation of blood coagulation and clot lysis. The measurements are performed in four test channels of the disposable cartridge which enable differential testing with different sets of reagents without the need for any reagent preparation or controlled pipetting. The cartridge utilizes a citrated evacuated blood collection tube filled with a patient whole blood sample. The proprietary technology SEER Sonorheometry measures the evolution of shear modulus (i.e., clot stiffness) in all four channels as a function of time. The QStat Cartridge is intended for use in patients 18 years or older by professionals in a hospital setting (point of care or laboratory) to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.

Each QStat Cartridge is pre-filled with lyophilized reagent beads individually sealed in an airtight pouch. After a QStat Cartridge is removed from its primary packaging, it is inserted into the instrument dock. A whole blood sample, collected in a 3.2% sodium citrate anticoagulant blood collection tube (minimum volume 2.7 mL), is attached directly to the cartridge and the test is initiated using the touch screen interface on the Quantra Hemostasis Analyzer. The cartridge is the only component of the Quantra System that is in direct contact with blood. The fluidic system within the instrument draws the sample into the cartridge where it is warmed to 37°C, aliquoted, introduced and mixed with the lyophilized reagents, and analyzed. When the test is complete, the cartridge is released from the dock to be disposed of in an appropriate biosafety sharps container.

**Table 1** summarizes the lyophilized reagents contained in each cartridge channel of the QStat Cartridge and the output parameter reported. Clot times and clot stiffness values obtained from the measurements performed by the QStat Cartridge are combined to form parameters that depict the functional status of the patient’s coagulation system. Four (4) of the parameters are measured and two (2) are calculated. The assay provides the following information for each patient sample: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS) and Clot Stability to Lysis (CSL).

**Table 1. QStat Cartridge Output Parameters**

Channel	Reagents	QStat Cartridge Output Parameter (units of measure)
1	Kaolin, calcium buffers & stabilizers	Clot Time (CT) (seconds)
2	Thromboplastin, tranexamic acid (TXA), polybrene, calcium, buffers, and stabilizers	No direct output (see calculated parameters)
3	Thromboplastin, polybrene, calcium, buffers & stabilizers	Clot Stiffness (CS) (hectoPascals)
4	Thromboplastin, polybrene, abciximab, calcium, buffers & stabilizers	Fibrinogen Contribution (FCS) (hectoPascals)
<b>Calculated Parameters</b>		
2&3	See above	Clot Stability to Lysis (CSL) (percent)
3&4	See above	Platelet Contribution to Clot Stiffness (PCS) (hectoPascals)

The analyzer displays the test results (n=5) in three different views: dial display screen, stiffness curves data, and trend screen. The dial display screen is the primary viewing screen and has a dial for each of the five output parameters. Each dial shows the reference range, assay measurement range, parameter abbreviation, and the numerical result for the corresponding parameter. The stiffness curves are a graphical display of shear modulus measurements over time that enable the user to view the development of clot stiffness over time. The trends screen displays results from a patient for up to six time points.

There are two levels of external QStat Controls (QSL1 and QSL2) that are supplied separately (required but not provided materials) for testing on the Quantra System when changing cartridge lots, changing control lots, or after significant changes are made to the Quantra instrument (e.g., software update).

**DEVICE MODIFICATION DESCRIPTION**

The QStat Cartridge was initially cleared under K213917 for liver transplantation and trauma patients. An additional submission (K240045) added a sample matrix claim of arterial whole blood. This 510(k) adds the peripartum obstetric patient as an additional patient population.

## TECHNOLOGICAL COMPARISON

The software version used for this submission version is 2.4.1. This is the same version used for previous submission K240045. This version does not change any output from the Quantra Instrument or QStat Cartridge cleared in DEN180017 or K213917.

## SUBSTANTIAL EQUIVALENCE INFORMATION

*Predicate Device Name:* QStat Cartridge

*Predicate 510(k) Number:* K240045

*Comparison with the Predicate:*

**Table 2** provides an overall comparison of the modified QStat Cartridge with the previously cleared QStat Cartridge.

**Table 2: Comparison between K240045 and Modified QStat Cartridge**

	Modified Device	Predicate Device
	Quantra System (Subject of 510(k))	Quantra QStat System (K240045)
<b>Similarities</b>		
<b>Manufacturer</b>	HemoSonics, LLC	Same
<b>Trade Name</b>	Quantra QStat Cartridge	Same
<b>Common Name</b>	Whole Blood Hemostasis System	Same
<b>Classification Name</b>	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients	Same
<b>Regulation Number</b>	21 CFR 864.5430	Same
<b>Product Code</b>	QFR	Same
<b>Device Class</b>	II	Same
<b>Location of Use</b>	Point of care and laboratory settings	Same
<b>Disposables</b>	QStat Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)	Same
<b>Analyzer Hardware</b>	Quantra Hemostasis Analyzer HS-002	Same
<b>Reagents</b>	<u>Channel 1</u> : Kaolin, Calcium <u>Channel 2</u> : Thromboplastin, Calcium, Polybrene, Tranexamic Acid <u>Channel 3</u> : Thromboplastin, Calcium, Polybrene <u>Channel 4</u> : Thromboplastin, Calcium, Polybrene, Abciximab	Same
<b>Test Results</b>	CT, CS, PCS, FCS, CSL	Same

	<b>Modified Device</b>	<b>Predicate Device</b>
	<b>Quantra System (Subject of 510(k))</b>	<b>Quantra QStat System (K240045)</b>
<b>Differences</b>		
<b>Indications for use</b>	<p>The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous <b>or</b> arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.</p> <p>The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).</p> <p>The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma, liver transplantation, and peripartum obstetric procedures.</p> <p>Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.</p> <p>For prescription use only.</p>	<p>The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous <b>or</b> arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.</p> <p>The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).</p> <p>The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.</p> <p>Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.</p> <p>For prescription use only.</p>
<b>Analyzer Software</b>	Ver 2.4.1	Same

## NON-CLINICAL AND CLINICAL TESTS SUMMARY AND CONCLUSIONS

An analytical specificity study was conducted to evaluate potential sources of exogenous interference in the obstetric patient population for the QStat Cartridge on the Quantra.

The Interference Study included screening studies evaluating the following potential interferents: hemabate (carboprost tromethamine), methergine (methylergonovine maleate), misoprostol, and oxytocin (Pitocin). The study involved testing each potential interferent with normal and hypercoagulable whole blood specimens as a screening study. In screening studies, potential sources of interference were tested both at one (1) level of interferent (“Test”) and without interferent (“Control”). The number of replicates at each level of a screening study was targeted to provide a 95% confidence interval (2-sided), per CLSI EP07-A2 Guideline.

The clinical performance of the Quantra Hemostasis Analyzer with the QStat Cartridge was evaluated in a multi-center prospective observational study involving parturients 18 years or older undergoing labored or non-labored delivery for which there was a concern for coagulopathy. Three hundred twenty-two subjects were eligible for this study across seven clinical sites in the US. Results from the QStat Cartridge were compared to equivalent results from the ROTEM delta or TEG 5000 as well as conventional coagulation testing (aPTT, PT/INR, fibrinogen level, platelet count). Testing was performed upon ordering standard of care coagulation testing or viscoelastic testing for suspected coagulopathy and, in some cases, at the time of hemorrhage or after hemorrhage when blood products or other interventions were delivered for up to 4 samples per patient.

Correlation and clinical agreement analyses were performed to compare measurements obtained with the QStat Cartridge to comparable measures obtained with the ROTEM delta or TEG 5000.

For the analytical specificity study, the highest concentration of each substance tested showed no significant interference in whole blood samples collected in 3.2% sodium citrate anticoagulant collection tubes.

For the method comparison study, a clinical agreement analysis was performed to evaluate the ability of the QStat CSL parameter to identify fibrinolytic samples relative to the ROTEM delta lysis parameter EXTEM ML. The overall agreement of patient sample assignments into lysis-positive and lysis-negative based on data for QStat CSL and ROTEM delta EXTEM ML was 92%.

The correlation between QStat FCS and fibrinogen levels was assessed using Passing-Bablok regression analysis. Results showed good agreement between the methods (slope =1,  $r=0.815$ ) albeit with a constant bias.