510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251404

B Applicant

HemoSonics, LLC

C Proprietary and Established Names

QStat Cartridge

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QFR	Class II	21 CFR 864.5430 - Coagulation System for The Measurement Of Whole Blood Viscoelastic Properties In Perioperative Patients	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Expansion in indications for use to include patients undergoing peripartum obstetric procedures.

B Measurand:

Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL)

C Type of Test:

Semi-quantitative

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For in vitro diagnostic use

D Special Instrument Requirements:

Quantra Hemostasis Analyzer

IV Device/System Characteristics:

A Device Description:

The QStat Cartridge is a single-use, multi-channel disposable plastic cartridge used with the Quantra Hemostasis Analyzer to assess a patient's coagulation and clot lysis in a clinical setting (point-of-care or clinical laboratory) during trauma, liver transplantation and peripartum obstetric procedures. The QStat cartridge consists of four independent test channels that can be tested simultaneously with Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry.

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.

Each channel of the cartridge contains prefilled lyophilized reagents in the form of beads that enable differential testing without the need for any reagent preparation or pipetting before testing. 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).

QStat Cartridge Reagents and Test function per Channel

Channel	Reagents	QStat Cartridge Output Parameter (units of measure)
Measured Parameters		
1	Kaolin, calcium, buffers, and 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, and stabilizers	**Clot Stiffness (CS)** (hectopascals)
4	Thromboplastin, polybrene, abciximab, calcium, buffers, and stabilizers	**Fibrinogen Contribution to Clot Stiffness (FCS**) (hectopascals)
Calculated Parameters		
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 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). QC is manufactured by HemoSonics and will be commercially available separately from the Quantra Hemostasis Analyzer and QStat Cartridge. The QSL1 and QSL2 are recommended to be run monthly, changing cartridge lots, changing control lots, or after significant changes are made to the Quantra instrument (e.g., software update). QSL1 and QSL2 are reconstituted by the end user with the provided diluent and loaded onto the QStat by the same method as patient samples. The plastic diluent vial is shipped with an extender that serves to guide the vial into the cartridge's

evacuated sample tube attachment, after reconstitution. The QStat Controls contain materials to test the measured output parameters for the QStat Cartridge: CT, CS, and FCS, as well as the calculated parameters, CSL and PCS.

Principle of Operation:

The QStat Cartridge uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, which uses ultrasonic pulses to quantify the shear modulus (i.e., stiffness) of a blood sample during the process of coagulation and clot lysis. A focused ultrasound pulse is transmitted into the blood sample to generate a shear wave, causing the sample to resonate once the clot begins to form. Multiple parameters measured from the four channels of the cartridge provide information about the functional role of the coagulation factors, fibrinogen, platelets, and clot lysis factors in the sample.

Clot Time (CT) Test
CT is directly measured in Channel #1 using kaolin to provide contact surface activation of coagulation via the intrinsic pathway. Kaolin is an aluminum silicate mineral with a negatively charged surface. Calcium acetate is included to re-calcify the blood sample used for testing. Prolongation of the intrinsic pathway clot time is likely due to deficiencies in intrinsic pathway coagulation factors, presence of anticoagulants, or inhibitors that affect the intrinsic pathway.

Clot Stiffness (CS) Test
CS is directly measured in Channel #3 and is determined by measuring the stiffness after the clot has formed using thromboplastin (tissue factor) to activate the extrinsic pathway of coagulation. The test includes polybrene, a reagent that neutralizes heparin. Calcium acetate is included to re-calcify the blood sample used for testing. This test allows an evaluation of the total clot stiffness from the combined contributions from both platelets and fibrinogen.

Fibrinogen Contribution to Clot Stiffness (FCS) Test
FCS is directly measured in Channel #4 using thromboplastin (tissue factor) to activate the extrinsic pathway of coagulation, in combination with a reagent that inhibits platelet aggregation and contraction (Abciximab). Abciximab is the Fab fragment of a monoclonal antibody that binds on the platelet surface receptor GPIIb/IIIa. Polybrene is included to neutralize heparin in addition to calcium acetate to re-calcify the blood sample used for testing. This test allows an evaluation of the contribution of functional fibrinogen to clot stiffness without the effect of heparin anticoagulation. In addition, when used in combination with the Clot Stiffness (CS) Test, the contribution of platelets to the clot stiffness can be determined.

Two additional functional parameters are calculated:

Platelet Contribution to Clot Stiffness (PCS)
PCS is a functional parameter that is calculated as the difference between the overall CS measured in Channel #3 and the FCS measured in Channel #4, reported in hectopascals (hPa).

Clot Stability to Lysis (CSL)
CSL is a functional parameter that is calculated from Channel #2 and #3 and is reported as a percent after the maximum stiffness in Channel #3 is detected. The CSL reports the loss in clot stiffness that is likely due to the influence of fibrinolysis on a scale from 100% (no clot lysis) to 10% (significant clot degradation).

V Substantial Equivalence Information:

A Predicate Device Name(s):
QStat Cartridge, ROTEM *delta* Thromboelastometry System, EXTEM Assay, FIBTEM Assay, APTEM Assay for ROTEM *delta* Thromboelastometry System

B Predicate 510(k) Number(s):
K213917, K083842, K101533

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251404	K240045	K083842	K101533
Device Trade Name	QStat Cartridge	QStat Cartridge	ROTEM *delta* Thromboelastometry System	EXTEM Assay, FIBTEM Assay, APTEM Assay for the ROTEM *delta* Thromboelastometry System
General Device Characteristic Similarities				
Intended Use/Indications For Use	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	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 whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic	The ROTEM *delta* Thromboelastometry System is designed for in vitro diagnostic use by professionals in a laboratory environment. The ROTEM® *delta* is intended to provide a qualitative and quantitative indication of the coagulation state of a blood sample. For this purpose the ROTEM *delta*	The EXTEM assay is a semi-quantitative in vitro diagnostic assay used to monitor the coagulation process via the extrinsic pathway in citrated whole blood specimens on the ROTEM *delta* Thromboelastometry System. Clotting characteristics are described by the functional parameters Clotting Time

	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	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 and liver	records the clot firmness changes in a sample of citrated whole blood as the sample clots, retracts and lyses in real time. The analyzer output consists of a qualitative graphical representation (mirrored coagulation curve – clot firmness over time) and several defined numerical parameters describing the curve quantitatively. The in-TEM assay is a semi-quantitative in vitro diagnostic assay used to monitor the coagulation process via the intrinsic pathway in citrated whole blood specimens. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)). The	(CT), Speed of Clot formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)), CFT and alpha (Speed of Clot Formation) are complementary parameters and should be used in conjunction with the main parameters Clotting Time (CT) and Clot Firmness (A20/MCF). The FIBTEM assay is a semi-quantitative in vitro diagnostic assay on the ROTEM *delta* Thromboelastometry System to monitor the clot firmness of a citrated whole blood specimen after blocking platelet contribution to the clot firmness. The fibTEM® is always used in conjunction with exTEM® Clotting characteristics are described by the functional parameter Clot Firmness (A20/MCF). The

	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.	transplantation procedures. Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis. For prescription use only.	assay is intended for professional use in the clinical laboratory on the ROTEM *delta* Instrument. The hep-TEM assay is a semi-quantitative in vitro diagnostic assay used to monitor the coagulation process via the intrinsic pathway in the presence of heparin, in citrated whole blood specimens. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)). The assay is intended for professional use in the clinical laboratory on the ROTEM *delta* Instrument. The NATEM assay is a semi-quantitative in vitro diagnostic assay used to monitor the coagulation process contact activated by the	APTEM® assay is a semi-quantitative in vitro diagnostic assay on the ROTEM *delta* Thromboelastometry System to monitor the clot firmness of a citrated whole blood specimen after blocking hyperfibrinolysis by aprotinin. The ap-TEM is always used in conjunction with ex-TEM. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)). CFT and alpha (Speed of Clot Formation) are complementary parameters and should be used in conjunction with the main parameters Clotting Time (CT) and Clot Firmness (A20/MCF). Each assay, APTEM, EXTEM and

			surface of the measurement cell, in citrated whole blood specimens. Clotting characteristics are described by the functional parameters Clotting Time (CT), Speed of Clot formation (CFT and alpha angle), Clot Firmness (A20/MCF) and Clot Lysis (LOT, ML, LI(x)). The assay is intended for professional use in the clinical laboratory on the ROTEM *delta* Instrument. The star-TEM reagent is intended for use as recalcification reagent in the NATEM and in-TEM on the ROTEM *delta* Thromboelastometry System.	FIBTEM is performed on the ROTEM *delta* analyzer which has the following indication for use: The indication for ROTEM® *delta* is in adult patients when an evaluation of their blood coagulation properties is desired. Coagulation evaluations with the ROTEM® *delta* system are commonly used to assess clinical conditions in organ transplantation, cardiovascular surgery, cardiology procedures and trauma to access post-operative hemorrhage and/or thrombosis.
Sample Type	3.2% sodium citrated whole blood, 3.2% citrated arterial whole blood	3.2% sodium citrated whole blood	Citrated whole blood	Citrated whole blood
Results Display	Graphical (curves) and numerical display of patient results	Same	Same	Same
Measurands	Clot time (CT)	Same	Same	Same
	Clot Stiffness (CS)	Same	Same Reported as	Same Reported as

			EXTEM A20 (Clot Firmness)	EXTEM A20 (Clot Firmness)
	Fibrinogen Contribution to Clot Stiffness (FCS)	Same	Same Reported as FIBTEM A20	Same Reported as FIBTEM A20
Reagents (extrinsic pathway)	Thromboplastin	Same	Same	Same
General Device Characteristic Differences				
Sample Volume	3.0 mL citrated whole blood sample (2.7 mL whole blood + citrate)	Same	300 µL per assay (in-TEM Assay, hep-TEM Assay, NATEM Assay, star-TEM)	300 µL per assay (EXTEM Assay, FIBTEM Assay, APTEM Assay)
Sample Preparation	Automated	Automated	Manual	Manual
Signal Generation	Ultrasonic pulses directed into a stationary well	Same	Oscillating pin in stationary cup	Oscillating pin in stationary cup
Assay Output	Platelet Contribution to Clot Stiffness (PCS)	Same	Output not directly provided but can be calculated offline from comparison of EXTEM and FIBTEM	Output not directly provided but can be calculated offline from comparison of EXTEM and FIBTEM
	Clot Stability to Lysis (CSL)	Same	EXTEM and APTEM ML/LI60 and difference calculated offline.	EXTEM and APTEM ML/LI60 and difference calculated offline.
Reagents	Kaolin (intrinsic pathway activator)	Same	Ellagic acid (intrinsic pathway activator)	Ellagic acid (intrinsic pathway activator)
	Abciximan (platelet inhibitor)	Same	Cytochalasin D (platelet inhibitor)	Cytochalasin D (platelet inhibitor)
	Tranexamic acid (fibrinolysis inhibitor)	Same	Aprotinin (fibrinolysis inhibitor)	Aprotinin (fibrinolysis inhibitor)

Principle of Operation	SEER Sonorheometry uses ultrasound pulses to quantify the shear modulus (i.e., stiffness) of a blood sample during the process of coagulation and clot lysis. A focused ultrasound pulse is transmitted into the blood sample to generate a shear wave, causing the sample to resonate once the clot begins to form.	Same	Shear elasticity of a coagulating sample by motion of an oscillating pin in a stationary cup. The motion of the pin is detected by an optical detection system. Data are processed and analyzed by a computer with special software.	Shear elasticity of a coagulating sample by motion of an oscillating pin in a stationary cup. The motion of the pin is detected by an optical detection system. Data are processed and analyzed by a computer with special software.

VI Standards/Guidance Documents Referenced:

CLSI EP28: *Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition*

CLSI EP07: *Interference Testing in Clinical Chemistry; Approved Guideline Third Edition*

CLSI EP09: *Measurement Procedure Comparison and Bias Estimation Using Patient Samples, Third Edition*

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   Refer to K213917.

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

The interference study evaluated the following potential interferents: hemabate (carboprost tromethamine), methergine (methylergonovine maleate), misoprostol, and oxytocin (Pitocin) and involved testing of each interferent with normal and hypercoagulable whole blood specimens. Hypercoagulable specimens consisted of fibrinogen-spiked specimens (whole blood with elevated fibrinogen). Potential sources of interference were tested both at one level of interferent ("Test") and without interferent ("Control").

Each exogenous interferent was tested with normal whole blood and hypercoagulable fibrinogen-spiked whole blood. If interference was observed for either specimen, the concentration at which interference occurred for that specimen would be identified by a dose-response study. If no interference was observed, additional studies were performed with the remaining two hypercoagulable sample types. If no interference was observed for normal whole blood and the three (3) hypercoagulable specimen types an analyte was considered to not interfere up to the highest level tested, then no additional testing was performed.

The following table shows the highest concentration at which each substance showed no significant interference in whole blood samples collected in 3.2% sodium citrate anticoagulant collection tubes.

Potential Interferent	Concentration
Hemabate	9.291 ng/mL
Methergine	17.754 ng/mL
Misoprostol	2.43 ng/mL
Oxytocin	0.09 ng/mL

4. Assay Reportable Range:

QStat Output Parameter	Units	Reportable Ranges
Clot Time (CT)	Seconds	60 – 480
Clot Stability to Lysis (CSL)	Percent	10 – 100
Clot Stiffness (CS)	hectopascals	2 – 65
Platelet Contribution to Clot Stiffness (PCS)	hectopascals	2 – 50
Fibrinogen Contribution to Clot Stiffness (FCS)	hectopascals	0.2 -30

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Refer to K213917.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   a. Comparison with ROTEM delta Thromboelastometry System:
   The clinical performance of the QStat Cartridge and the predicate device, ROTEM delta Thromboelastometry System, was evaluated in a multi-center prospective observational study across seven clinical sites in the US involving patients 18 years of age or older. The study included 308 obstetric patients undergoing labored or non-labored delivery for which there was a concern for coagulopathy and 14 healthy, non-pregnant females from which contrived samples were prepared.

   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. Contrived samples (6.98%) were prepared by spiking blood samples from normal volunteers with tPA and heparin to broaden the range of comparisons between QStat Cartridge parameters and ROTEM delta parameters. All blood samples were run in parallel on the Quantra QStat Cartridge and the ROTEM delta.

   Correlation and clinical agreement analysis were performed to compare measurements obtained with the QStat Cartridge to comparable measures obtained with the ROTEM delta Thromboelastometry System. A linear regression analysis was performed to evaluate the correlation between the QStat parameters and comparable ROTEM delta Thromboelastometry System parameters. For the primary analysis, samples were combined with contrived samples. For the analysis of parameter CT vs INTEM CT, samples from the obstetric study (n=195) were combined with samples from liver transplant and trauma subjects (K213917) to span the analytical measurement range due to the difficulty in obtaining hypocoagulable samples in the peripartum obstetric population. The results met the pre-defined acceptance criteria.

Parameter	N	Sample Range	Linear Fit	Slope Estimate (95% CI)	Intercept Estimate (95% CI)	Pearson (95% CI)
CT vs INTEM CT	585	60-480	CT=67.8+ 0.38* INTEM CT	0.38 (0.36, 0.40)	67.8 (62.9, 72.6)	0.88 (0.86, 0.90)
CS vs EXTEM A20 (hPa)	301	4.0-62	CS= -2.522+ 2.910* EXTEM A20	2.910 (2.766,3.053)	-2.522 (-4.1-1.0)	0.917 (0.897,0.933)
PCS vs PLATEM (hPa)	302	4.0-48	PCS = -0.181+ 2.622*PLATEM	2.622 (2.458, 2.785)	-0.181 (-1.71,1.347)	0.877 (0.847, 0.900)
FCS vs FIBTEM A20 (hPa)	299	0.9-23	FCS=-0.169+3.233* FIBTEM A20	3.233 (2.974,3.492)	-0.169 (-0.55,0.213)	0.817 (0.776, 0.851)

A clinical agreement analysis was performed to evaluate the ability of the QStat CSL parameter to identify fibrinolytic samples relative to the comparable ROTEM delta Thromboelastometry System 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 99%. Agreement within the lysis-positive and lysis-negative subcategories was 85% and 99%, respectively. These results met the acceptance criteria for overall and subcategory agreements.

Clinical Agreement Analysis for Comparison of QStat and ROTEM delta Lysis Parameters

ROTEM delta EXTEM ML				
QUANTRA QStat CSL		**Lysis Positive***	**Lysis Negative***	**Total**
	Lysis Positive**	11	1	12
	Lysis Negative**	2	231	233
	Total	13	232	245

**Classification based on Quantra definition of lysis
* Classification based on ROTEM definitions of lysis

Summary Metrics for Clinical Agreement Analysis for Comparison of QStat and ROTEM delta Lysis Parameters

Category	Agreement (95% CI)
Lysis Positive	0.85 (0.54, 0.97)
Lysis Negative	0.99 (0.97, 1.0)
Overall	0.99 (0.96, 1.0)

b. Comparison with Teg 5000 Hemostasis System:
At two clinical sites, 60 samples were analyzed on the QStat Cartridge and the TEG 5000 Hemostasis System. For the correlation analysis, TEG 5000 clot stiffness amplitudes were first converted to units of clot elasticity (hPa). The limited data set was not supplemented with contrived samples, did not span the analytical measuring range, and did not meet the predefined acceptance criteria.

Parameter	N	Linear Fit	Slope Estimate (95% CI)	Intercept Estimate (95% CI)	Pearson R (95% CI)
CT vs CK-R	60	CT=81.129+ 7.240* CK-R	7.240 (4.906,9.575)	81.129 (69.37,92.88)	0.624 (0.435,0.755)
CS vs CK-MA (hPa)	60	CS= 0.438+ 2.221* TEG MA	2.221 (1.653,2.79)	0.438 (-8.21,9.087)	0.709 (0.551.0.814)

Clinical Agreement Analysis for Comparison of QStat Cartridge CSL and TEG 5000 LY30

		TEG 5000 LY30		
QUANTRA QStat® CSL		**Lysis Positive***	**Lysis Negative***	**Total**
	Lysis Positive**	0	0	0
	Lysis Negative**	0	57	57
	Total	0	57	57

**Classification based on Quantra definition of lysis
* Classification based on TEG 500 definition of lysis

Overall, the agreement between QStat CSL and TEG 5000 LY30 was 100%.

c. Comparison with Conventional Coagulation Tests:
To assess the clinical agreement of QStat test results with results from corresponding conventional coagulation tests (aPTT, fibrinogen, platelet count), samples were categorized as “Low” (decrease in coagulation function) or “Not Low” (adequate or increase in coagulation function) based on clinical guidelines to demonstrate concordance in hypocoagulable samples for the obstetric patient population. The results met the predefined acceptance criteria for overall and subcategory agreements.

	N in Category CT vs aPTT	Agreement CT vs aPTT	N in Category PCS vs Platelets/Fib	Agreement PCS vs Platelet/Fib
Low (L)	9/9	1.0 (0.63, 1.0)	14/15	0.93 (0.66, 1.0)
Not Low (NL)	300/309	0.97 (0.94, 0.99)	266/290	0.92 (0.88, 0.95)
Overall	309/318	0.97 (0.95, 0.99)	280/305	0.92 (0.88, 0.95)

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Reader Study
A reader study was conducted to assess the ability of potential users of Quantra System with the QStat cartridge to correctly interpret results displayed on the Quantra dials display and curve screen for samples analyzed on the QStat Cartridge from obstetric patients. The QStat reader study was conducted with a total of 9 readers who were clinicians who regularly assess the blood coagulation status of patients. Participants were presented with views of Quantra dial displays and curve screens representing a variety of test outcomes that can be anticipated from obstetric patients. For each of 10 cases, a dials display screen was provided containing 5 dials with results for all 5 QStat parameters: CT, CSL, CS, PCS, and FCS. The curves screen showing clot stiffness over time of the 4 test channels was also provided for 2 cases. Each participant answered a total of 60 multiple choice questions for a total of 540 multiple-choice questions. For all QStat parameters, >95% of questions pertaining to each of the displays were answered correctly.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The reference range study was a multi-center, prospective, observational study aimed at establishing reference range intervals in obstetric patients for the test parameters measured using the Quantra QStat System with the QStat Cartridge. The study population consisted of 129 healthy women (≥18 to 45 years of age) who were pregnant with a single fetus and duration of pregnancy was ≥28 weeks enrolled across three (3) external sites that are representative of the

general population of the United States. The distribution of the study population was approximately equal across the following categories: 28-32 weeks, 33-36 weeks, >36 weeks.

Output Parameter	Units	N	Reference Range
Clot Time (CT)	Seconds	129	97 – 147
Clot Stability to Lysis (CSL)	Percent	125	94 – 100*
Clot Stiffness (CS)	hectopascals	128	18.2 – 48.3
Platelet Contribution to Clot Stiffness (PCS)	hectopascals	128	15.6 – 40.8
Fibrinogen Contribution to Clot Stiffness (FCS)	hectopascals	129	2.2 – 8.4

*The Clot Stability to Lysis (CSL) is a calculated parameter. Samples with CSL values below 90% are indicative of reduction of clot stiffness that is likely due to the influence of fibrinolysis. The 90% threshold was calculated as the lower bound of the 95% confidence interval around the lower limit of the reference interval for CSL determined in healthy volunteers.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.