July 8, 2022

Tem Innovations GmbH
David Jacob
Head of Quality Assurance and Regulatory Affairs, PBM
Martin-Kollar-Strasse 15
Munich, Bavaria 81829 DEU

Re: K201440
Trade/Device Name: ROTEM sigma Thromboelastometry System
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: May 29, 2020
Received: June 1, 2020

Dear David Jacob:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu
Branch Chief
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201440

Device Name
ROTEM sigma Thromboelastometry System

Indications for Use *(Describe)*
The ROTEM sigma thromboelastometry system is a fully integrated and automated in vitro diagnostic system designed to monitor and analyze a patient's coagulation status by measuring the viscoelastic properties of a 3.2% citrated venous or arterial whole blood sample. The ROTEM sigma system is indicated for use with adult patients 21 years and older where a semi-quantitative evaluation of their blood coagulation properties is desired, in the point of care and laboratory settings. Coagulation evaluations on the ROTEM sigma instrument, together with the ROTEM sigma complete + hep cartridge, are used to assess peri-operative hemorrhage and/or thrombosis in cardiovascular surgery and liver transplantation.
The single use, multichannel cartridge ROTEM sigma complete + hep contains the following assays:
INTEM C is a semi-quantitative assay used to monitor coagulation via the intrinsic pathway in citrated whole blood samples.
EXTEM C is a semi-quantitative assay used to monitor coagulation via the extrinsic pathway in citrated whole blood samples.
FIBTEM C is a semi-quantitative assay used to monitor coagulation via the extrinsic pathway in citrated whole blood samples, after blocking platelet contribution to clot firmness.
HEPTEM C is a semi-quantitative assay used to monitor coagulation via the intrinsic pathway in citrated whole blood samples, after inactivating heparin.
Results from the ROTEM sigma should not be the sole basis for a patient diagnosis; ROTEM sigma results should be considered along with a clinical assessment of the patient's condition and other laboratory tests.
For in vitro Diagnostic Use.
For professional 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

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

Summary Information

Submitter's Information:	Tem Innovations GmbH Martin-Kollar-Strasse 15 81829 Munich, Germany	
Contact Person:	David Jacob Phone: + 49 89 45 42 95 23 Fax: + 49 89 45 42 95 22 Email: djacob@werfen.com	
Preparation Date:	7 July 2022	
Device Trade Names:	Instrument:	ROTEM *sigma*
	Assay Cartridge:	ROTEM *sigma* complete + hep
Regulatory Information:	Common or Usual Name:	Thromboelastometry System
	Classification Name:	Multipurpose System for In Vitro Coagulation Studies (21 CFR 864.5425)
	Regulatory Class:	Class II
	Product Code:	JPA
	Classification Panel:	Hematology (81)
Predicate Device:	K083842: ROTEM *delta* Thromboelastometry System K101533: EX-TEM, FIB-TEM, and AP-TEM for ROTEM *delta* Thromboelastometry System	

Device Information

Device Description: The ROTEM *sigma* is an in vitro diagnostic (IVD) whole blood hemostasis system intended for use in the evaluation of coagulopathies in Point of Care (POC) or laboratory settings. It uses rotational thromboelastometry to provide semi-quantitative information about the coagulation state of a blood sample. The ROTEM *sigma* system records the kinetic changes in a sample of 3.2% citrated whole blood during clot formation, as well as when the sample clot retracts and/or lyses.

Several parameters are measured and reported for this purpose. The graphical presentation reflects the various physiological results, which describe the interaction between coagulation factors and inhibitors, fibrinogen, platelets, and the fibrinolysis system. Additionally, the effect of certain drugs influencing hemostasis, in particular some anticoagulants (e.g. heparin), can be detected.

Test Principle:

The ROTEM *sigma* technology uses rotational thromboelastometry that is based on a fixed cylindrical cup and an oscillating vertical axis.

The axis is supported by a high precision ball bearing and oscillates through an angle of 4.75°. The oscillation of the axis is driven by a motor that is connected to the axis via a spring. For the measurement, the channel's measurement axis engages the plastic pin in the cup of the disposable heated cartridge holding the blood sample.

The oscillation is detected optically via a mirror plate at the upper end of the axis, which reflects the light from a diode light source onto a light sensitive sensor. If no clotting takes place, the pin movement is not restricted. As a clot forms and attaches itself between the pin and cup surfaces, the pin movement becomes increasingly restricted. The result is a balance between the spring tension and the tension of the clot. As the clot becomes firmer, the oscillation amplitude of the axis is reduced.

The ROTEM *sigma* assays are based on the principle of either

- intrinsic coagulation activation with or without the presence of heparin, or
- extrinsic coagulation activation with or without the presence of platelet inhibitors.

Indications for Use / Intended Use:

The ROTEM *sigma* thromboelastometry system is a fully integrated and automated *in vitro* diagnostic system designed to monitor and analyze a patient's coagulation status by measuring the viscoelastic properties of a 3.2% citrated venous or arterial whole blood sample. The ROTEM *sigma* system is indicated for use with adult patients 21 years and older where a semi-quantitative evaluation of their blood coagulation properties is desired, in the point of care and laboratory settings. Coagulation evaluations on the ROTEM *sigma* instrument, together with the ROTEM *sigma* complete + hep cartridge, are used to assess peri-operative hemorrhage and/or thrombosis in cardiovascular surgery and liver transplantation.

The single use, multichannel cartridge ROTEM *sigma* complete + hep contains the following assays:

INTEM C is a semi-quantitative assay used to monitor coagulation via the intrinsic pathway in citrated whole blood samples.

EXTEM C is a semi-quantitative assay used to monitor coagulation via the extrinsic pathway in citrated whole blood samples.

FIBTEM C is a semi-quantitative assay used to monitor coagulation via the extrinsic pathway in citrated whole blood samples, after blocking platelet contribution to clot firmness.

HEPTEM C is a semi-quantitative assay used to monitor coagulation via the intrinsic pathway in citrated whole blood samples, after inactivating heparin.

Results from the ROTEM *sigma* should not be the sole basis for a patient diagnosis; ROTEM *sigma* results should be considered along with a clinical assessment of the patient's condition and other laboratory tests.

For *in vitro* Diagnostic Use.

For professional use only.

Comparison to Predicates

The ROTEM *sigma* thromboelastometry system is compared below to the predicate device, the ROTEM *delta* thromboelastometry system (K083842, K101533).

Comparison of Technological Characteristics with the Predicate Device - System

Characteristic	**Subject Device** **ROTEM *sigma***	**Predicate Device** **ROTEM *delta*** **(K083842, K101533)**
Similarities		
Instrument	Fully Integrated Thromboelastometry Instrument	
Measuring Technique	Shear elasticity of a coagulating sample by motion of a pin	
Measuring Channels utilized	4	
Signal Generation	Oscillating pin in a stationary cup	
Signal Transducer	Optical system with CCD sensor	
Sample	3.2 % citrated whole blood	
Measurement Station Temperature	37 °C ± 1 °C	
Graphical Presentation of Results	Presents each assay reaction curve and parameters in real time “TEMogram”	
Differences		
Cups & Pins	Cups and pins are integrated into assay cartridges	Cups and pins need to be installed in instrument for each test
Sample Handling	Automated sample transfer	Manual pipetting, electronic pipette
Sample Volume	≥ 2.7 mL sample tube for four assays	300 µL per assay
Supply Voltage	110/240 V_{AC}, 60/50 Hz, max. 210 VA	115/230 V_{AC}, 60/50 Hz, max. 350 VA
Environment	• Temperature ○ Operating: 18 °C - 30 °C ○ Storage: 0 °C - 50 °C • Relative Humidity ○ Operating: 40 % - 60 % ○ Storage: 20% - 85% • Operable to 3000 m above sea level	• Temperature ○ Operating: 15 °C - 30 °C ○ Storage: 0 °C - 50 °C • Relative Humidity 20 % - 85 % • Operable to 2000 m above sea level
Reported Parameters	• Clotting Time “CT” • Amplitude “A(x)” (A5, A10, A20) • Maximum Clot Firmness “MCF” • Lysis Index “LI60” • Maximum Lysis “ML”	• Clotting Time “CT” • Clot Formation Time “CFT” • Alpha angle “α” • Amplitude “A(x)” (A10, A20) • Maximum Clot Firmness “MCF” • Lysis Index “LI(x)” (LI30, LI60) • Maximum Lysis “ML” • Lysis Onset Time “LOT”

Characteristic	Subject Device ROTEM *sigma*	Predicate Device ROTEM *delta* (K083842, K101533)
Controls	• ROTEM *sigma* ROTROL N (Level 1 Control) • ROTEM *sigma* ROTROL P (Level 2 Control) • ROTEM *sigma* System QC cartridge	• ROTROL N (Level 1 Control) • ROTROL P (Level 2 Control)
Assays	• INTEM C • EXTEM C • FIBTEM C • HEPTEM C	• INTEM • EXTEM • FIBTEM • APTEM • HEPTEM • NATEM
Assay Format	All four assays (reagents) provided ready-to-use in the single-use ROTEM *sigma* complete + hep cartridge.	Assay reagents provided in separate vials. Preparation required to create the desired assay.
Reagent Form	Lyophilized beads	Liquid or lyophilisate with a diluent (HEPTEM only)
Reagent Handling	Cartridges containing assay reagents are stored at room temperature. No warmup required.	Assay reagents require refrigeration, 5-15 min warmup required (depending on room temperature).

Comparison of Technological Characteristics with the Predicate Device - Assays

Characteristic	Subject Device ROTEM *sigma*	Predicate Device ROTEM *delta* (K083842/K101533)
Assay Name	**INTEM C**	**INTEM**
Similarities		
Activation Principle	Intrinsic coagulation activation • Recalcification of a sample • Activation of the intrinsic coagulation pathway	
Activation Reagents	• $CaCl_2$ • Ellagic Acid	
Assay Name	**EXTEM C**	**EXTEM**
Similarities		
Activation Principle	Extrinsic coagulation activation • Recalcification of a sample • Activation of the extrinsic coagulation pathway	
Activation Reagents	• $CaCl_2$ • Recombinant Tissue Factor • Heparin Inhibitor	
Assay Name	**FIBTEM C**	**FIBTEM**
Similarities		
Activation Principle	Extrinsic coagulation activation in the presence of platelet inhibitors • Recalcification of a sample • Activation of the extrinsic pathway • In vitro inhibition of platelets	
Activation Reagents	• $CaCl_2$ • Recombinant Tissue Factor • Heparin Inhibitor • Platelet Inhibitors	
Assay Name	**HEPTEM C**	**HEPTEM**
Similarities		
Activation Principle	Intrinsic coagulation activation in the presence of heparin • Recalcification of a sample • Activation of the intrinsic coagulation pathway • In vitro inactivation of heparin	
Activation Reagents	• $CaCl_2$ • Ellagic Acid • Heparin Inhibitor	

Performance Summary

Electrical Safety and Electromagnetic Compatibility (EMC)

The ROTEM *sigma* system was tested to the following Electrical Safety and EMC standards: IEC 61010-1:2010, AMD1:2016, IEC 61010-2-010:2014, IEC 61010-2-101:2015, IEC 61326-1:2012, IEC 61326-2-6: 2012, and 47 CFR 15 Subpart B:2018. The ROTEM *sigma* has also been tested to and passes the limits of IEC 60601-1-2:2014.

Precision

An internal precision study was performed on three (3) lots of ROTEM *sigma* complete + hep cartridges using whole blood (normal, contrived hypocoagulable, contrived hypercoagulable) and three (3) lots each of the controls ROTEM *sigma* ROTROL N and ROTEM *sigma* ROTROL P. The control study was run in duplicate, twice a day for twenty (20) days, for a total of eighty (80) replicates per control. The whole blood study was run in triplicate in one (1) day on five (5) ROTEM *sigma* instruments, for a total of fifteen (15) replicates per sample type. The highest % CV of the three (3) lots for the parameters CT, A5, A10, A20, and MCF are summarized below.

Precision Summary

Assay	Parameter	ROTROL N		ROTROL P		Normal Whole Blood	Contrived Hypocoagulable Samples	Contrived Hypercoagulable Samples
		% CV (Within-Run)	% CV (Within-Laboratory)	% CV (Within-Run)	% CV (Within-Laboratory)	% CV (Within-Laboratory)	% CV (Within-Laboratory)	% CV (Within-Laboratory)
INTEM C	CT (s)	7.7	8.7	4.6	4.9	3.8	6.8	4.5
	A5 (mm)	2.0	2.1	7.0	7.2	4.2	3.5	3.9
	A10 (mm)	2.0	2.0	6.1	6.2	2.9	3.2	2.8
	A20 (mm)	1.6	1.6	7.9	8.2	1.9	2.6	1.6
	MCF* (mm)	1.5	1.6	8.5	8.7	1.8	2.8	1.4
EXTEM C	CT (s)	9.6	9.7	6.5	7.1	6.8	13.6	13.6
	A5 (mm)	2.4	2.8	4.9	5.2	5.0	5.2	3.0
	A10 (mm)	1.8	2.2	4.3	4.4	3.3	4.1	2.4
	A20 (mm)	1.6	1.7	5.1	5.3	2.6	3.9	1.9
	MCF* (mm)	1.4	1.5	5.6	5.9	2.3	4.8	1.4
FIBTEM C	A5 (mm)	2.6	2.8	7.2	7.3	10.2	N/A	4.7
	A10 (mm)	2.2	2.6	5.4	5.4	9.7	N/A	4.7
	A20 (mm)	2.0	2.2	4.5	4.5	7.4	N/A	4.2
	MCF* (mm)	1.7	1.8	5.2	5.3	9.8	N/A	4.6
HEPTEM C	CT (s)	4.1	4.3	4.7	5.6	3.9	9.4	2.3
	A5 (mm)	1.9	2.1	5.5	5.5	5.7	9.5	3.5
	A10 (mm)	1.8	1.9	5.6	5.7	3.9	8.4	2.5
	A20 (mm)	1.6	1.7	6.1	6.1	2.9	8.5	1.6
	MCF* (mm)	1.3	1.5	6.6	6.7	2.5	7.9	1.6

* While the whole blood study used MCF, the controls study used as time point 30 minutes after CT because ROTROL controls reach maximum amplitude (MCF) by that time.

Performance Summary (Cont.)

Precision (Cont.)

A second precision study was performed to support the precision of the lysis parameters. This study was performed on three (3) lots of ROTEM *sigma* complete + hep cartridges using normal whole blood and abnormal hyperfibrinolysis blood. The study was run on five (5) ROTEM *sigma* instruments with three (3) replicates/instrument, for a total of fifteen (15) replicates per sample type and cartridge lot. The highest SD and/or % CV of the three (3) lots for the parameters LI60 and ML are summarized below.

Lysis Precision Summary

Assay	Parameter	Normal Whole Blood Within-Laboratory %CV	Abnormal Hyperfibrinolysis Blood Within-Laboratory SD
INTEM C	LI60 (%)	1.5	0.6
EXTEM C		1.4	1.4

Assay	Parameter	Normal Whole Blood Within-Laboratory SD	Abnormal Hyperfibrinolysis Blood Within-Laboratory %CV
INTEM C	ML* (%)	1.4	0.6
EXTEM C		1.3	1.4

* calculated at 60 minutes after CT

Performance Summary (Cont.)

Precision (Cont.)

A third precision study was performed to support the precision of the lot-to-lot variability. This study was performed on three (3) lots of the ROTEM *sigma* complete + hep cartridges using normal donor whole blood. The study was run in triplicate, twice a day for five (5) days, for a total of thirty (30) replicates per cartridge lot. The results are summarized below.

Lot-to-Lot Variability Summary

Assay	Parameter	N	Mean	Within-Lot		Between-Lot	
				SD	%CV	SD	%CV
INTEM C	CT (s)	90	183.8	9.0	4.9	0.0	0.0
	A5 (mm)	90	43.9	3.9	8.9	0.0	0.0
	A10 (mm)	90	54.1	4.1	7.5	0.0	0.0
	A20 (mm)	90	60.5	4.4	7.3	0.0	0.0
	MCF (mm)	90	62.0	5.1	8.1	0.0	0.0
	LI60 (%)	90	96.9	2.1	2.2	0.0	0.0
	ML* (%)	90	3.1	2.1	67.9	0.0	0.0
EXTEM C	CT (s)	90	58.3	5.1	8.8	0.0	0.0
	A5 (mm)	90	44.2	3.9	8.9	0.0	0.0
	A10 (mm)	90	54.5	4.1	7.4	0.0	0.0
	A20 (mm)	90	61.6	4.2	6.7	0.0	0.0
	MCF (mm)	90	63.9	4.7	7.4	0.0	0.0
	LI60 (%)	90	97.6	1.7	1.8	0.0	0.0
	ML* (%)	90	2.4	1.7	73.1	0.0	0.0
FIBTEM C	A5 (mm)	90	11.7	3.0	25.9	0.0	0.0
	A10 (mm)	90	12.7	3.3	25.8	0.0	0.0
	A20 (mm)	90	13.5	3.4	25.0	0.0	0.0
	MCF (mm)	90	13.8	3.5	25.6	0.0	0.0
HEPTEM C	CT (s)	90	182.7	10.3	5.6	0.4	0.2
	A5 (mm)	90	41.1	3.6	8.7	0.0	0.0
	A10 (mm)	90	51.8	3.7	7.1	0.0	0.0
	A20 (mm)	90	58.9	4.0	6.8	0.0	0.0
	MCF (mm)	90	60.9	4.7	7.7	0.0	0.0

* calculated at 60 minutes after CT

Performance Summary (Cont.)

Reproducibility

Reproducibility studies were performed at three (3) external clinical sites on one (1) lot of ROTEM *sigma* complete + hep cartridges using four (4) ROTEM *sigma* instruments per site and three (3) lots each of the controls ROTEM *sigma* ROTROL N and ROTEM *sigma* ROTROL P. The study was run in triplicate twice a day for five (5) days, for a total of thirty (30) replicates per control. The pooled data from three (3) external sites for all sites together and each individual site are presented below.

Reproducibility Summary - All Sites - ROTROL N

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility (Within-Control Lot)		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	270	344.8	24.6	7.1	0.0	0.0	1.4	0.4	3.6	1.0	24.9	7.2	9.0	2.6
	A5 (mm)	270	43.8	0.7	1.6	0.1	0.2	0.2	0.4	0.3	0.7	0.8	1.8	0.0	0.0
	A10 (mm)	270	47.4	0.7	1.4	0.0	0.0	0.3	0.6	0.5	1.0	0.9	1.9	0.0	0.0
	A20 (mm)	270	51.2	0.7	1.4	0.0	0.1	0.3	0.5	0.6	1.1	1.0	1.9	0.0	0.0
	MCF(mm)	270	55.0	0.8	1.4	0.4	0.7	0.2	0.4	0.7	1.3	1.1	2.1	0.0	0.0
EXTEM C	CT (s)	270	130.2	13.6	10.4	2.9	2.2	0.0	0.0	1.7	1.3	14.0	10.7	3.3	2.5
	A5 (mm)	270	43.6	0.9	2.1	0.3	0.7	0.0	0.0	0.2	0.4	1.0	2.3	0.4	0.9
	A10 (mm)	270	47.7	0.9	1.8	0.3	0.6	0.0	0.0	0.1	0.3	0.9	2.0	0.4	0.8
	A20 (mm)	270	52.1	0.8	1.5	0.3	0.5	0.0	0.0	0.2	0.4	0.8	1.6	0.3	0.6
	MCF(mm)	270	56.9	0.9	1.6	0.2	0.4	0.0	0.0	0.3	0.6	1.0	1.7	0.2	0.3
FIBTEM C	A5 (mm)	269*	37.8	1.2	3.2	0.4	1.1	0.0	0.0	0.3	0.9	1.3	3.5	0.7	1.9
	A10 (mm)	269*	42.3	1.2	2.8	0.4	1.0	0.0	0.0	0.3	0.7	1.3	3.1	0.7	1.6
	A20 (mm)	269*	47.1	1.1	2.3	0.4	0.9	0.0	0.0	0.3	0.7	1.2	2.6	0.5	1.2
	MCF(mm)	269*	52.9	1.1	2.0	0.4	0.8	0.0	0.0	0.6	1.1	1.3	2.5	0.3	0.5
HEPTEM C	CT (s)	270	332.6	20.8	6.3	0.0	0.0	5.1	1.5	0.0	0.0	21.4	6.4	10.7	3.2
	A5 (mm)	270	43.1	0.8	1.9	0.0	0.0	0.0	0.0	0.7	1.6	1.1	2.5	0.0	0.0
	A10 (mm)	270	46.9	0.9	1.8	0.0	0.0	0.1	0.3	0.8	1.8	1.2	2.5	0.0	0.0
	A20 (mm)	270	51.0	0.8	1.6	0.0	0.0	0.1	0.2	0.8	1.6	1.1	2.2	0.0	0.0
	MCF(mm)	270	54.9	0.8	1.5	0.3	0.5	0.1	0.1	0.9	1.6	1.2	2.3	0.0	0.0

* No FIBTEM data provided for one sample.

Reproducibility Summary - All Sites - ROTROL P

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility (Within-Control Lot)		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	270	365.3	9.6	2.6	4.5	1.2	2.3	0.6	3.5	0.9	11.4	3.1	63.0	17.2
	A5 (mm)	270	24.3	1.1	4.4	0.4	1.6	0.0	0.0	0.3	1.1	1.2	4.8	0.0	0.0
	A10 (mm)	270	27.0	1.1	4.1	0.5	2.0	0.0	0.0	0.2	0.7	1.3	4.6	0.0	0.0
	A20 (mm)	270	29.5	1.2	4.1	0.6	2.0	0.0	0.0	0.3	0.9	1.4	4.7	0.0	0.0
	MCF(mm)	270	31.7	1.3	4.2	0.6	1.9	0.0	0.0	0.3	1.0	1.5	4.7	0.0	0.0
EXTEM C	CT (s)	270	146.7	6.0	4.1	0.0	0.0	2.4	1.6	3.8	2.6	7.5	5.1	0.7	0.5
	A5 (mm)	270	24.8	1.3	5.1	0.5	2.1	0.0	0.0	0.2	0.7	1.4	5.5	0.2	0.7
	A10 (mm)	270	27.7	1.3	4.8	0.6	2.3	0.0	0.0	0.3	1.0	1.5	5.4	0.0	0.0
	A20 (mm)	270	30.3	1.4	4.6	0.7	2.3	0.0	0.0	0.2	0.8	1.6	5.2	0.1	0.5
	MCF(mm)	270	32.7	1.5	4.6	0.7	2.2	0.0	0.0	0.1	0.2	1.7	5.1	0.2	0.7
FIBTEM C	A5 (mm)	270	24.8	1.2	5.0	0.4	1.8	0.0	0.0	0.4	1.5	1.4	5.5	0.0	0.0
	A10 (mm)	270	27.7	1.3	4.8	0.5	1.9	0.0	0.0	0.4	1.5	1.5	5.4	0.0	0.0
	A20 (mm)	270	30.4	1.5	4.8	0.5	1.8	0.0	0.0	0.5	1.6	1.6	5.4	0.0	0.0
	MCF(mm)	270	33.1	1.6	4.7	0.7	2.0	0.0	0.0	0.3	1.0	1.7	5.2	0.0	0.0
HEPTEM C	CT (s)	270	367.4	10.7	2.9	4.7	1.3	2.3	0.6	9.0	2.5	14.9	4.1	66.8	18.2
	A5 (mm)	270	25.1	1.1	4.5	0.5	1.8	0.0	0.0	0.9	3.7	1.5	6.1	0.0	0.0
	A10 (mm)	270	27.9	1.2	4.3	0.4	1.5	0.0	0.0	0.9	3.1	1.5	5.5	0.0	0.0
	A20 (mm)	270	30.4	1.3	4.2	0.6	2.0	0.0	0.0	0.8	2.6	1.6	5.3	0.0	0.0
	MCF(mm)	270	32.5	1.4	4.2	0.7	2.1	0.0	0.0	0.8	2.6	1.7	5.4	0.0	0.0

Performance Summary (Cont.)

Reproducibility (Cont.)

Reproducibility Summary - Site 1 - ROTROL N

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	345.3	32.7	9.5	0.0	0.0	3.6	1.1	32.9	9.5	13.8	4.0
	A5 (mm)	90	43.4	0.8	1.9	0.3	0.6	0.0	0.0	0.9	2.0	0.1	0.2
	A10 (mm)	90	46.8	0.7	1.5	0.0	0.0	0.1	0.3	0.7	1.6	0.1	0.3
	A20 (mm)	90	50.5	0.8	1.6	0.3	0.6	0.1	0.2	0.9	1.7	0.0	0.0
	MCF(mm)	90	54.2	0.8	1.4	0.3	0.5	0.0	0.0	0.8	1.5	0.1	0.2
EXTEM C	CT (s)	90	132.0	14.2	10.7	5.8	4.4	1.5	1.1	15.4	11.7	5.4	4.1
	A5 (mm)	90	43.4	0.8	1.9	0.3	0.7	0.0	0.0	0.9	2.0	0.2	0.6
	A10 (mm)	90	47.7	0.9	1.8	0.4	0.7	0.0	0.0	0.9	1.9	0.2	0.4
	A20 (mm)	90	52.1	0.7	1.3	0.3	0.5	0.0	0.0	0.7	1.4	0.0	0.0
	MCF(mm)	90	56.7	0.7	1.3	0.3	0.5	0.0	0.0	0.8	1.3	0.2	0.4
FIBTEM C	A5 (mm)	90	37.8	1.5	4.0	0.0	0.0	0.0	0.0	1.5	4.0	0.7	1.9
	A10 (mm)	90	42.3	1.4	3.4	0.0	0.0	0.0	0.0	1.4	3.4	0.6	1.5
	A20 (mm)	90	47.0	1.3	2.7	0.0	0.0	0.0	0.0	1.3	2.7	0.4	0.9
	MCF(mm)	90	52.5	1.2	2.3	0.0	0.0	0.2	0.5	1.2	2.3	0.4	0.7
HEPTEM C	CT (s)	90	333.0	24.1	7.2	0.0	0.0	5.1	1.5	24.6	7.4	14.2	4.3
	A5 (mm)	90	42.9	0.8	1.9	0.0	0.0	0.0	0.0	0.8	1.9	0.2	0.4
	A10 (mm)	90	46.5	0.8	1.7	0.0	0.0	0.0	0.0	0.8	1.7	0.1	0.2
	A20 (mm)	90	50.6	0.8	1.6	0.0	0.0	0.0	0.0	0.8	1.6	0.1	0.2
	MCF(mm)	90	54.5	0.7	1.3	0.0	0.0	0.0	0.0	0.7	1.3	0.2	0.4

Reproducibility Summary - Site 1 - ROTROL P

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	365.7	8.5	2.3	1.8	0.5	1.3	0.3	8.7	2.4	63.3	17.3
	A5 (mm)	90	24.2	0.9	3.6	0.6	2.3	0.0	0.0	1.0	4.3	0.2	0.7
	A10 (mm)	90	27.0	0.9	3.4	0.7	2.6	0.0	0.0	1.2	4.3	0.1	0.5
	A20 (mm)	90	29.6	1.0	3.5	0.7	2.5	0.0	0.0	1.3	4.3	0.2	0.6
	MCF(mm)	90	31.6	1.1	3.4	0.8	2.6	0.0	0.0	1.4	4.3	0.3	0.9
EXTEM C	CT (s)	90	146.2	6.1	4.1	0.0	0.0	1.3	0.9	6.2	4.2	2.3	1.6
	A5 (mm)	90	25.0	1.2	4.8	0.7	2.7	0.0	0.0	1.4	5.5	0.2	0.9
	A10 (mm)	90	28.1	1.2	4.2	0.8	2.8	0.0	0.0	1.4	5.1	0.3	1.0
	A20 (mm)	90	30.7	1.3	4.3	0.7	2.4	0.0	0.0	1.5	5.0	0.4	1.2
	MCF(mm)	90	33.0	1.3	4.0	0.8	2.5	0.0	0.0	1.6	4.7	0.4	1.3
FIBTEM C	A5 (mm)	90	25.2	1.0	3.9	0.7	2.9	0.0	0.0	1.2	4.9	0.0	0.0
	A10 (mm)	90	28.2	1.0	3.6	0.8	2.7	0.0	0.0	1.3	4.5	0.0	0.0
	A20 (mm)	90	30.9	1.1	3.7	0.8	2.5	0.0	0.0	1.4	4.5	0.0	0.0
	MCF(mm)	90	33.5	1.2	3.6	0.9	2.7	0.0	0.0	1.5	4.5	0.0	0.0
HEPTEM C	CT (s)	90	369.4	9.6	2.6	3.2	0.9	0.0	0.0	10.1	2.7	65.5	17.7
	A5 (mm)	90	24.4	0.9	3.6	0.6	2.3	0.0	0.0	1.0	4.3	0.3	1.2
	A10 (mm)	90	27.2	0.8	3.1	0.7	2.6	0.0	0.0	1.1	4.0	0.3	1.0
	A20 (mm)	90	29.7	1.0	3.4	0.9	2.9	0.0	0.0	1.3	4.4	0.3	0.9
	MCF(mm)	90	31.7	1.1	3.4	0.9	2.8	0.0	0.0	1.4	4.4	0.4	1.2

Performance Summary (Cont.)

Reproducibility (Cont.)

Reproducibility Summary - Site 2 - ROTROL N

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	346.1	18.2	5.3	6.0	1.7	0.0	0.0	19.2	5.5	8.5	2.5
	A5 (mm)	90	43.9	0.6	1.4	0.0	0.0	0.3	0.6	0.7	1.5	0.0	0.0
	A10 (mm)	90	47.6	0.7	1.4	0.0	0.0	0.3	0.6	0.7	1.6	0.0	0.0
	A20 (mm)	90	51.4	0.7	1.4	0.0	0.0	0.2	0.5	0.8	1.5	0.0	0.0
	MCF(mm)	90	55.2	0.6	1.1	0.3	0.6	0.4	0.7	0.8	1.5	0.0	0.0
EXTEM C	CT (s)	90	130.5	12.7	9.7	2.2	1.7	0.0	0.0	12.9	9.9	1.6	1.3
	A5 (mm)	90	43.5	0.9	2.1	0.5	1.2	0.0	0.0	1.1	2.4	0.4	0.9
	A10 (mm)	90	47.6	0.8	1.7	0.4	0.9	0.0	0.0	0.9	1.9	0.4	0.8
	A20 (mm)	90	51.9	0.8	1.5	0.4	0.7	0.0	0.0	0.8	1.6	0.4	0.7
	MCF(mm)	90	56.8	0.9	1.5	0.0	0.0	0.4	0.6	0.9	1.7	0.2	0.4
FIBTEM C	A5 (mm)	90	37.5	0.9	2.5	0.7	2.0	0.0	0.0	1.2	3.2	1.0	2.6
	A10 (mm)	90	42.0	1.0	2.3	0.8	1.9	0.0	0.0	1.3	3.0	0.9	2.2
	A20 (mm)	90	47.0	1.0	2.1	0.7	1.5	0.0	0.0	1.2	2.6	0.9	1.8
	MCF(mm)	90	52.7	1.0	1.9	0.5	1.0	0.2	0.4	1.1	2.1	0.8	1.5
HEPTEM C	CT (s)	90	333.1	16.5	4.9	2.2	0.7	1.8	0.5	16.7	5.0	8.5	2.6
	A5 (mm)	90	42.6	0.8	1.9	0.1	0.3	0.2	0.5	0.8	2.0	0.0	0.0
	A10 (mm)	90	46.3	0.9	2.0	0.0	0.0	0.2	0.5	0.9	2.0	0.0	0.0
	A20 (mm)	90	50.4	0.8	1.6	0.0	0.0	0.2	0.5	0.8	1.7	0.0	0.0
	MCF(mm)	90	54.3	0.8	1.5	0.4	0.8	0.3	0.5	1.0	1.8	0.0	0.0

Reproducibility Summary Site 2 - ROTROL P

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	368.6	10.3	2.8	2.6	0.7	1.6	0.4	10.7	2.9	61.8	16.8
	A5 (mm)	90	24.0	1.5	6.1	0.4	1.6	0.0	0.0	1.5	6.3	0.0	0.0
	A10 (mm)	90	26.8	1.5	5.7	0.5	1.8	0.0	0.0	1.6	6.0	0.0	0.1
	A20 (mm)	90	29.3	1.7	5.9	0.6	2.1	0.0	0.0	1.8	6.2	0.1	0.2
	MCF(mm)	90	31.4	1.8	5.7	0.4	1.2	0.3	0.8	1.9	5.9	0.0	0.0
EXTEM C	CT (s)	90	150.7	5.2	3.4	2.2	1.4	0.0	0.0	5.6	3.7	0.8	0.5
	A5 (mm)	90	24.6	1.6	6.5	0.5	2.2	0.0	0.0	1.7	6.9	0.0	0.0
	A10 (mm)	90	27.5	1.7	6.3	0.8	2.8	0.0	0.0	1.9	6.9	0.0	0.0
	A20 (mm)	90	30.2	1.8	6.1	0.8	2.7	0.0	0.0	2.0	6.6	0.0	0.0
	MCF(mm)	90	32.6	2.0	6.1	0.9	2.6	0.0	0.0	2.2	6.6	0.0	0.0
FIBTEM C	A5 (mm)	90	24.5	1.6	6.7	0.2	0.8	0.0	0.0	1.6	6.7	0.1	0.6
	A10 (mm)	90	27.4	1.8	6.7	0.4	1.4	0.0	0.0	1.9	6.8	0.0	0.0
	A20 (mm)	90	30.1	2.0	6.7	0.3	1.1	0.0	0.0	2.0	6.8	0.2	0.7
	MCF(mm)	90	32.9	2.2	6.6	0.5	1.4	0.0	0.0	2.2	6.7	0.0	0.0
HEPTEM C	CT (s)	90	374.8	10.4	2.8	2.8	0.7	4.1	1.1	11.5	3.1	69.8	18.6
	A5 (mm)	90	24.8	1.5	5.9	0.6	2.3	0.0	0.0	1.6	6.3	0.3	1.3
	A10 (mm)	90	27.6	1.6	5.9	0.3	1.0	0.0	0.0	1.7	6.0	0.0	0.0
	A20 (mm)	90	30.2	1.7	5.7	0.6	2.1	0.0	0.0	1.8	6.1	0.0	0.0
	MCF(mm)	90	32.3	1.8	5.6	0.7	2.3	0.0	0.0	2.0	6.0	0.0	0.0

Performance Summary (Cont.)

Reproducibility (Cont.)

Reproducibility Summary - Site 3 - ROTROL N

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	343.0	20.3	5.9	0.0	0.0	3.9	1.1	20.7	6.0	6.4	1.9
	A5 (mm)	90	44.1	0.6	1.4	0.0	0.0	0.3	0.6	0.7	1.5	0.0	0.0
	A10 (mm)	90	47.7	0.6	1.3	0.0	0.0	0.4	0.8	0.7	1.5	0.0	0.0
	A20 (mm)	90	51.6	0.6	1.2	0.0	0.0	0.4	0.7	0.7	1.4	0.0	0.0
	MCF(mm)	90	55.5	0.9	1.7	0.5	1.0	0.2	0.4	1.1	2.0	0.2	0.3
EXTEM C	CT (s)	90	128.2	13.9	10.8	0.0	0.0	1.3	1.0	13.9	10.8	2.9	2.2
	A5 (mm)	90	43.9	1.0	2.3	0.0	0.0	0.0	0.0	1.0	2.3	0.5	1.2
	A10 (mm)	90	47.9	1.0	2.0	0.0	0.0	0.0	0.0	1.0	2.0	0.5	1.1
	A20 (mm)	90	52.2	0.8	1.6	0.2	0.4	0.0	0.0	0.9	1.7	0.5	1.0
	MCF(mm)	90	57.3	1.1	1.8	0.4	0.7	0.0	0.0	1.1	2.0	0.3	0.5
FIBTEM C	A5 (mm)	89*	38.2	1.1	2.9	0.4	1.0	0.0	0.0	1.2	3.1	0.5	1.4
	A10 (mm)	89*	42.6	1.1	2.6	0.5	1.1	0.0	0.0	1.2	2.9	0.5	1.2
	A20 (mm)	89*	47.5	1.1	2.2	0.5	1.0	0.0	0.0	1.2	2.5	0.4	0.8
	MCF(mm)	89*	53.6	1.1	2.0	0.7	1.3	0.0	0.0	1.3	2.3	0.2	0.3
HEPTEM C	CT (s)	90	331.8	21.2	6.4	0.0	0.0	6.9	2.1	22.3	6.7	8.4	2.5
	A5 (mm)	90	43.9	0.9	2.0	0.0	0.0	0.0	0.0	0.9	2.0	0.2	0.5
	A10 (mm)	90	47.9	0.9	1.8	0.0	0.0	0.1	0.3	0.9	1.8	0.2	0.4
	A20 (mm)	90	51.9	0.8	1.5	0.0	0.	0.0	0.0	0.8	1.5	0.1	0.2
	MCF(mm)	90	55.9	1.0	1.8	0.3	0.5	0.0	0.0	1.0	1.9	0.1	0.1

* No FIBTEM data provided for one sample.

Reproducibility Summary Site 3 - ROTROL P

Assay	Parameter	N	Mean	Repeatability		Between-Run		Between-Day		Within-Control Lot		Between-Control Lot	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
INTEM C	CT (s)	90	361.5	10.0	2.8	7.1	2.0	3.4	0.9	12.7	3.5	63.9	17.7
	A5 (mm)	90	24.6	0.7	2.7	0.1	0.6	0.0	0.2	0.7	2.8	0.2	0.9
	A10 (mm)	90	27.3	0.7	2.6	0.4	1.4	0.0	0.0	0.8	3.0	0.2	0.7
	A20 (mm)	90	29.8	0.7	2.2	0.4	1.4	0.0	0.0	0.8	2.6	0.1	0.5
	MCF(mm)	90	32.0	0.9	2.8	0.5	1.6	0.0	0.0	1.0	3.2	0.3	1.0
EXTEM C	CT (s)	90	143.4	6.6	4.6	0.0	0.0	3.9	2.7	7.7	5.4	3.8	2.7
	A5 (mm)	90	24.7	0.8	3.3	0.2	1.0	0.4	1.4	0.9	3.8	0.3	1.1
	A10 (mm)	90	27.5	0.9	3.3	0.1	0.5	0.3	1.1	1.0	3.5	0.1	0.5
	A20 (mm)	90	30.1	0.8	2.8	0.5	1.5	0.3	1.0	1.0	3.3	0.2	0.6
	MCF(mm)	90	32.6	1.0	3.1	0.4	1.2	0.2	0.6	1.1	3.4	0.3	1.1
FIBTEM C	A5 (mm)	90	24.6	1.0	4.0	0.2	0.9	0.3	1.3	1.0	4.3	0.1	0.5
	A10 (mm)	90	27.5	1.0	3.6	0.3	1.2	0.2	0.6	1.1	3.8	0.3	0.9
	A20 (mm)	90	30.2	1.1	3.5	0.4	1.4	0.0	0.0	1.1	3.8	0.3	1.1
	MCF(mm)	90	32.9	1.1	3.2	0.6	1.8	0.0	0.0	1.2	3.7	0.4	1.2
HEPTEM C	CT (s)	90	357.9	11.9	3.3	6.9	1.9	2.9	0.8	14.0	3.9	65.8	18.4
	A5 (mm)	90	26.1	1.0	3.7	0.0	0.0	0.4	1.4	1.0	3.9	0.0	0.0
	A10 (mm)	90	28.9	1.0	3.3	0.0	0.0	0.4	1.4	1.0	3.6	0.0	0.0
	A20 (mm)	90	31.3	1.0	3.1	0.0	0.0	0.4	1.3	1.1	3.4	0.0	0.0
	MCF(mm)	90	33.4	1.1	3.3	0.3	0.8	0.3	0.9	1.2	3.5	0.1	0.3

Performance Summary (Cont.)

Interference

An interference study was performed using normal and hypocoagulable whole blood samples to determine the impact of interferents UF Heparin, LMW Heparin, Tranexamic Acid, ε-Aminocaproic Acid, Acetylsalicylic Acid (Aspirin), and Ticagrelor on the INTEM C, EXTEM C, FIBTEM C, and HEPTEM C assays. For each interferent, testing was performed with eight (8) replicates at three (3) interferent levels (Baseline, Claim, and Greater than Claim) for a total of twenty-four (24) replicates for each blood sample type. Because of its sensitivity to heparin, INTEM C was not tested for heparin interference. Another interference study was performed using normal whole blood samples to determine the impact of lupus anticoagulant on the same assays. This testing was performed with eleven (11) donors, each run on three (3) instruments with one (1) replicate per instrument. Testing confirmed no interference for INTEM C, EXTEM C, FIBTEM C, and HEPTEM C on the ROTEM *sigma* up to the following concentrations:

Interference Summary

Interferent	INTEM C	EXTEM C	FIBTEM C	HEPTEM C
UF Heparin	N/A	5 IU/mL	5 IU/mL	7 IU/mL
LMW Heparin	N/A	3 IU/mL	3 IU/mL	3 IU/mL
Tranexamic Acid	60 µg/mL	60 µg/mL	60 µg/mL	60 µg/mL
ε-Aminocaproic Acid	600 µg/mL	600 µg/mL	600 µg/mL	600 µg/mL
Acetylsalicylic Acid	3 mg/dL	3 mg/dL	3 mg/dL	3 mg/dL
Ticagrelor	0.1881 mg/dL	0.1881 mg/dL	0.1881 mg/dL	0.1881 mg/dL
Lupus Anticoagulant (dRVVT Screen/ Confirm Ratio)	1.34	1.34	1.34	1.34

Performance Summary (Cont.)

Reference Intervals

A total of one hundred twenty (120) whole blood samples from healthy donors were analyzed on the ROTEM *sigma* using ROTEM *sigma* complete + hep cartridges. The nonparametric, 95% reference interval along with two-sided, 90% confidence intervals around each limit were calculated.

Reference Intervals Summary

Parameter\Assay	INTEM C	EXTEM C	FIBTEM C	HEPTEM C
CT (s)	139 - 205	51 - 73	N/A	141 - 215
A5 (mm)	36 - 54	33 - 52	5 - 16	33 - 51
A10 (mm)	46 - 63	45 - 62	6 - 17	44 - 61
A20 (mm)	53 - 68	54 - 69	6 - 18	52 - 67
MCF (mm)	55 - 70	57 - 72	6 - 19	54 - 69
LI60 (%)	93 - 100	94 - 100	N/A	N/A
ML* (%)	0 - 7	0 - 6	N/A	N/A

* calculated at 60 minutes after CT

Reportable Ranges

The reportable ranges for the ROTEM *sigma* assays are based on the data of the method comparison and precision studies and presented below.

Reportable Ranges

Parameter\Assay	INTEM C	EXTEM C	FIBTEM C	HEPTEM C
CT (s)	123-365	45-172	N/A	122-376
A5 (mm)	11-66	13-69	2-33	10-59
A10 (mm)	16-74	18-77	2-36	15-68
A20 (mm)	21-78	23-81	2-38	20-73
MCF (mm)	24-79	25-82	2-41	24-75
LI60 (%)	0-100	0-100	N/A	N/A
ML* (%)	0-100	0-100	N/A	N/A

* calculated at 60 minutes after CT

Performance Summary (Cont.)

Method Comparison

A method comparison study was conducted at four (4) clinical sites comparing the ROTEM *sigma* to the predicate device, the ROTEM *delta* (K083842, K101533), using 3.2% citrated venous or arterial whole blood patient samples from the intended use populations and contrived samples.

The results for ROTEM *sigma* with ROTEM *sigma* complete + hep cartridges versus the ROTEM *delta* are presented below.

Method Comparison Summary

Assay	Parameter	N	Slope	Intercept	R
INTEM C	CT (s)	144	0.94	20.9	0.845
	A5 (mm)	144	0.91	3.8	0.977
	A10 (mm)	144	0.90	4.8	0.983
	A20 (mm)	144	0.92	4.5	0.985
	MCF (mm)	144	0.95	2.5	0.982
	LI60 (%)	148	1.00	1.0	0.990
	ML* (%)	148	1.00	-1.0	0.990
EXTEM C	CT (s)	183	1.17	-4.0	0.780
	A5 (mm)	183	0.94	5.1	0.953
	A10 (mm)	183	0.93	5.9	0.966
	A20 (mm)	183	0.95	4.7	0.973
	MCF (mm)	183	1.00	2.0	0.977
	LI60 (%)	187	1.00	1.0	0.982
	ML* (%)	187	1.00	-1.0	0.982
FIBTEM C	A5 (mm)	183	0.86	0.4	0.920
	A10 (mm)	183	0.89	0.3	0.921
	A20 (mm)	183	0.91	0.3	0.923
	MCF (mm)	183	1.00	-1.0	0.926
HEPTEM C	CT (s)	182	0.91	21.4	0.484
	A5 (mm)	182	0.92	3.1	0.940
	A10 (mm)	182	0.93	3.6	0.947
	A20 (mm)	182	0.95	3.0	0.959
	MCF (mm)	182	1.00	1.0	0.966

* calculated at 60 minutes after CT

Performance Summary (Cont.)

Arterial vs. Venous Study

A matrix comparison study using seventy-four (74) matched venous and arterial citrated whole blood samples was performed at two (2) external clinical sites to evaluate the difference in test results for venous and arterial blood on the EXTEM C, INTEM C, FIBTEM C, and HEPTEM C assays. The summary results for the pooled data are presented in the table below.

Arterial vs. Venous Study Summary

Assay	Parameter	N	Venous Mean	Arterial Mean	Mean Difference[1]	95% Confidence Interval	
INTEM C	CT (s)	58	480.5	449.2	1.4%	-5.6%	8.4%
	A5 (mm)	55	43.9	44.6	11.1%	-8.4%	30.6%
	A5 $(mm)^2$	54	44.5	44.5	1.6%	-2.4%	5.6%
	A10 (mm)	55	53.8	54.5	7.5%	-5.2%	20.2%
	A10 $(mm)^2$	54	54.6	54.4	1.6%	-2.9%	6.0%
	A20 (mm)	55	59.9	60.5	5.1%	-3.7%	13.9%
	A20 $(mm)^2$	54	60.6	60.4	1.5%	-3.6%	6.6%
	MCF (mm)	55	61.4	61.7	3.3%	-3.4%	10.1%
	LI60 (%)	54	96.4	95.7	-0.7%	-1.0%	-0.4%
	ML (%)	54	3.6	4.3	0.7% Lysis	0.4% Lysis	1.0% Lysis
EXTEM C	CT (s)	73	72.1	72.3	0.6%	-1.6%	2.7%
	A5 (mm)	73	46.2	46.5	1.0%	-0.2%	2.3%
	A10 (mm)	73	56.5	56.6	0.4%	-0.6%	1.3%
	A20 (mm)	73	63.1	63.1	0.0%	-0.8%	0.8%
	MCF (mm)	73	65.1	64.9	-0.2%	-0.9%	0.5%
	LI60 (%)	73	97.4	97.2	-0.2%	-0.4%	0.0%
	ML (%)	73	2.6	2.8	0.2% Lysis	0.0% Lysis	0.4% Lysis
FIBTEM C	A5 (mm)	71	14.2	14.3	0.9%	-1.0%	2.9%
	A10 (mm)	71	15.7	15.8	0.8%	-1.1%	2.6%
	A20 (mm)	71	17.0	17.1	0.8%	-0.6%	2.3%
	MCF (mm)	71	17.6	17.8	1.1%	-0.6%	2.9%
HEPTEM C	CT (s)	64	183.5	185.5	2.9%	-1.2%	6.9%
	A5 (mm)	64	43.0	43.7	1.7%	0.5%	2.9%
	A10 (mm)	64	53.4	54.2	1.5%	0.6%	2.4%
	A20 (mm)	64	60.2	60.7	0.8%	0.1%	1.5%
	MCF (mm)	64	62.3	62.2	0.0%	-0.7%	0.6%

[1] Mean difference is calculated from Bland-Altman plot.
[2] Outlier suppressed.

Conclusion

The technological and functional characteristics of the new ROTEM *sigma* system as described above are substantially equivalent to those of the predicate device (ROTEM *delta*, K083842/K101533).

The analytical and clinical study results demonstrate that the ROTEM *sigma* is safe and effective for its intended purpose and equivalent in performance to the predicate device (ROTEM *delta*, K083842/ K101533).