4.0 510(k) Summary

4.1 Submitter's name / Contact Person

AUG 10 2011

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4.2 Identification of the Product

Trade Name:	ROTEM® *delta* Thromboelastometry System ex-TEM® reagent fib-TEM® reagent ap-TEM® reagent
Common Name:	Whole Blood Haemostasis System
Classification Name:	Multipurpose System for *In Vitro* Coagulation Studies

4.3 Identification of the predicate

Thrombelastograph® Coagulation Analyzer (TEG®) – 5000 Series K002177, Product Code JPA, Haemoscope Corp.

4.4 Description of the Device

The three assays are system reagents for the previously cleared (K083842) ROTEM® *delta* Thromboelastometry system. For clarity, the description of ROTEM® *delta* Thromboelastometry analyzer is provided below.

The ROTEM® *delta* Thromboelastometry System consists of a four-column instrument (with integrated computer module, computer controlled electronic pipette, software), system reagents (in-TEM®,

hep-TEM®, star-TEM®, ex-TEM®, fib-TEM® and ap-TEM®), quality controls (ROTROL N, ROTROL P) and measurement cells (Cup and Pin pro). The blood sample is filled into a cylindrical cup. A pin oscillates permanently while it is immersed in the blood holding cup. The motion of the pin is detected by an optical detection system. Data are processed and analyzed by a computer with special software. If no clotting takes place, the movement of the pin is not obstructed. When a clot forms and attaches itself to the pin and cup surfaces, the movement is obstructed. As the clot becomes firmer, the rotational movement of the pin is reduced. The rotational movement of the pin is converted into amplitude with the following definitions applying to the thromboelastogram (TEM): Amplitude of 0 mm means unobstructed oscillation, while amplitude of 100 mm can be regarded as infinite firmness and blocking of the pin by the clot. The TEM amplitude is a measure of the clot firmness.

4.5 Intended Use

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*. 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 time) 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 specimens after blocking platelet contribution to the clot firmness. fib-TEM® is always used in conjunction with ex-TEM®. Clotting characteristics are described by the functional parameter Clot Firmness (A20/MCF).

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 specimens after blocking hyperfibrinolysis by aprotinin. 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 time) are

complementary parameters and should be used in conjunction with the main parameters Clotting Time (CT) and Clot Firmness (A20/MCF).

4.6 Summary of Technological Characteristics of the Product, Compared with the Predicate Device

	ROTEM® *delta*	TEG® 5000
Reagents / Accessories:		
Extrinsic Contact Activation Reagent	ex-TEM® (Rabbit brain thromboplastin)	Commercial thromboplastin (e.g. ex-TEM®)
Platelet Blocker Reagent	fib-TEM® (Cytochalasin D, $CaCl_2$)	Reopro®, $CaCl_2$
Antifibrinolytic drug	ap-TEM® (Aprotinin, $CaCl_2$)	Trasylol®, $CaCl_2$

*ex-TEM®, fib-TEM®, and ap-TEM® are the commercial names of the reagents used with the respective EXTEM, FIBTEM, and APTEM assays.

4.7 Executive Summary of the Study Report

The ROTEM® *delta (ROTEM)* Whole Blood Haemostasis System has recently been FDA cleared (K083842) using the TEG® 5000 (TEG) as a predicate device. In this study, the performance characteristics of the ex-TEM®, fib-TEM® and ap-TEM® reagents for ROTEM® *delta* were evaluated. For these three tests, no commercially available TEG® 5000 tests are available, but the TEG® 5000 User Manual lists on pp 11-13 recommendations on how to perform these tests using other manufacturers' reagents[1].

Based on the recommendations in the TEG® manual and the study protocol the three assays (EXTEM, FIBTEM and APTEM) were run on the ROTEM® and their equivalents (as described in the TEG® manual) were run on the predicate device, the TEG® in support of a 510(k) submission.

Tissue Factor (TF) is the common activator in all three tests on both ROTEM® and on TEG®. Detailed reagent compositions are shown in Table 2.

1) TEG® 5000 User's Manual. Version 4.2 Software. Remote and TEG-enabled versions. Haemoscope Corporation. Rev 02, 2006-04.

Table 2: Extrinsically activated tests as performed in ROTEM® and TEG®

ROTEM® / TEG® test	Activation Principle	Components (reagents) ROTEM®	Components (reagents) TEG®
EXTEM / TF activated	Tissue Factor (TF)	TF reagent (ex-TEM® rabbit brain thromboplastin), $CaCl_2$	TF reagent (ex-TEM® rabbit brain thromboplastin), $CaCl_2$
FIBTEM / Platelet Blocked	Tissue Factor (TF)	Cytochalasin D, $CaCl_2$ ex-TEM®	Reopro®, $CaCl_2$ TF reagent (ex-TEM®),
APTEM / Antifibrinolytic Drug	Tissue Factor (TF)	Aprotinin, $CaCl_2$ ex-TEM®	Trasylol® (aprotinin), $CaCl_2$ TF reagent (ex-TEM®),

ex-TEM® is the name of the TEM Innovations commercial brand of rabbit thromboplastin

The EXTEM assay run on the ROTEM® *delta* was compared to a "generic" tissue factor reagent run on the TEG® 5000 as recommended in the TEG® User Manual (page 12), The generic tissue factor chosen, was the ex-TEM reagent.

The FIBTEM assay (ex-TEM® reagent plus Cyochalasin D) run on the ROTEM®, was compared to the TF reagent plus ReoPro® run on the TEG® 5000 as recommended in the TEG® 5000 User Manual (page 13), ex-TEM® reagent was used as source of TF. Cyclochalasin D and ReoPro® are both potent platelet inhibitors that inhibit platelet almost completely[2,3]. ReoPro® is not incorporated into the FIBTEM assay because Cytochalasin D is not readily available for commercial use and is prohibitively expensive as it is an intravenous drug available by prescription only.

The APTEM assay (ex-TEM® reagent plus aprotinin) run on the ROTEM®, was compared the TF reagent with aprotinin run on the TEG® as recommended in the TEG® 5000 User Manual (page 13) for a hyperfibrinolysis confirmation test. The ex-TEM® reagent was used as source of TF. Trasylol® (Bayer) was used on the TEG® 5000 as recommended in the manual. A generic aprotinin, rather than Trasylol® is incorporated into the APTEM assay because Trasylol® is not readily available for commercial use as it is an intravenous drug available by prescription only.

2) Khurana S, Mattson J.C, Westley S, O'Neil W.W, Timmis G.C, Safian R.D. Monitoring platelet glycoprotein IIb/IIIa-fibrin interaction with tissue factor-activated thrombelastography. J. Lab Clin Med 1997; 4,:401-411

3) Lang T., Toller W. , Gütl M. , Mahla E. , Metzler H. , Rehak P. , März W. , Hallwachs-Baumann G. Different effects of abciximab and cytochalasin D on clot strength in thromboelastography. J Thromb Haemost 2004;2:147-53

For all three tests, the ROTEM® was shown to have good precision in its primary parameter clot firmness and adequate precision in its secondary coagulation kinetics parameters (see 4.8.2 – 4.8.4). The main parameters and their definitions are summarized in Table 2.
The method comparison with TEG® showed equality of the clot firmness (MCF vs. MA). The kinetic parameters (CT vs. R, CFT vs. K, Alpha Angle vs. Angle) showed a linear correlation between ROTEM® and TEG® (r>0.8).

Reference ranges for the ROTEM® test were estimated using the CSLI C28-A2 guideline on three clinical US reference sample groups. The reference ranges determined showed no significant center-to-center deviations and were in accordance with the reference ranges determined in earlier studies on European reference sample groups (Table 3).

Table 3: ROTEM® reference ranges from studies in Europe (EU) and US

		MCF (mm)	A20 (mm)	CT (sec)	CFT (sec)	Alpha (°) ROTEM®
EXTEM	EU	50-72	50-71	38-79	34-159	63-83
	US	51.7-70.3	50.2-69.8	43.2-81.6	47.6-126.8	65.0-80.0
FIBTEM	EU	9-25	8-24			
	US	7.0-24.0	7.0-23.8			

Three interfering substances widely used in coagulation management, the antifibrinolytic drugs aprotinin, tranexamic acid and epsilon-amino caproic acid (εACA) were investigated. Dose-response curves were investigated for heparin, for dilution and for urokinase on the EXTEM model in order to verify the diagnostic principles of thromboelastometric methods on ROTEM®.
In summary, ROTEM® is a precise Whole Blood Haemostasis System with the typical performance characteristics of a thrombelastographic method (no aprotinin interference on the extrinsically activated tests, high heparin insensitivity of the tests with extrinsic activation and sensitivity to dilution and lysis induced by urokinase in-vitro). Its reference ranges are reproducible from center to center.

The method comparison with TEG® shows equality of the primary parameter clot firmness and a linear regression and good correlation in the secondary kinetic parameters.
In aggregate the data presented in this report demonstrate that the ROTEM® system and the three assays described are substantially equivalent to the predicate TEG® System and corresponding assays.

4.8 Performance Data

4.8.1 Acceptance Criteria for Precision

The following tables show the Acceptance Criteria for ROTEM® reagents:

EXTEM/ FIBTEM/ APTEM:

Test	CT	CFT	Alpha	A20
Within-run Precision[1]	< 10 %	< 20 %	<5 %	<5 %
Between Operator Precision[2]	< 10 %	< 30%	<5 %	<6 %

[1] 5 runs on each of the 4 channels of one instrument testing healthy donor blood; CVs in highly pathological samples may vary
[2] 5 operators run ROTROL N in duplicates (only EXTEM)

For the FIBTEM test, only A20 applies.

4.8.2 EXTEM

Precision:

	CT CV (%)	CFT CV (%)	α-angle CV (%)	A20 CV (%)
Within-run[1]	4.4	5.5	1.4	1.9
Between-operator[2]	7.9	13.4	0.3	5.5

[1] 5 runs on each of the 4 channels of one instrument testing healthy donor blood; CVs in highly pathological samples may vary
[2] 5 operators run ROTROL N in duplicates

Interference:

Interference with the antifibrinolytic drugs aprotinin, tranexamic acid (TXA) and epsilon aminocaproic acid (EACA) was investigated.
No interference was seen on the EXTEM test with aprotinin (up to 400 kIU/ml spiked in whole blood).
No interference was found with tranexamic acid (up to 60 µg/ml) and EACA (up to 600 µg/ml spiked in whole blood, resp.).

Heparin responsiveness:

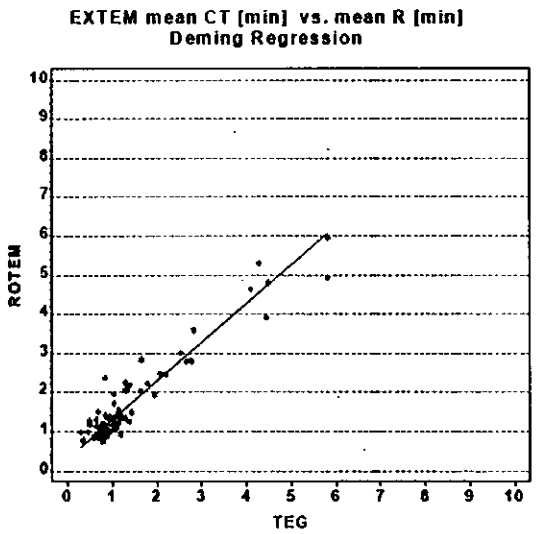
When using ex-TEM® as an activator the parameters are unaffected up to a heparin concentration of 4 U/ml UFH in whole blood (corresponding to app. 8 U/ml in the plasma).

Method comparison with TEG® 5000 Thrombelastograph (Haemoscope Corp, Niles, IL):

Method comparison studies were conducted in 3 US centers on patient samples. The patients enrolled comprised patients during surgery and post surgery at the intensive care unit (ICU). In order to broaden the range of comparison, contrived samples were added.
The extrinsically activated EXTEM test on ROTEM® *delta* was compared to an extrinsically activated tissue factor assay on TEG® 5000.

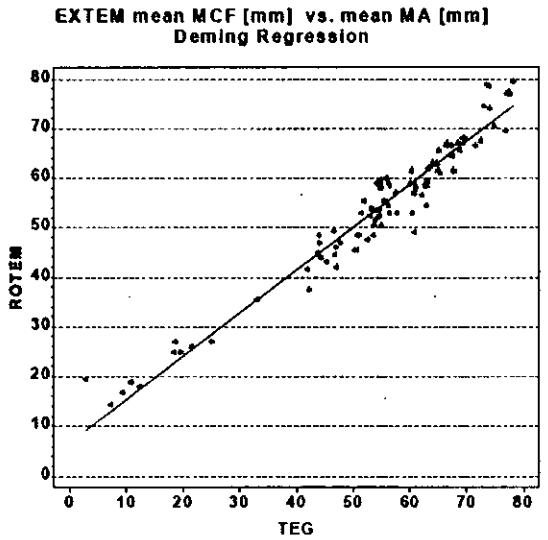
Scatter Plots
CT vs. R

CT: Clotting Time (ROTEM® *delta* parameter, usually in sec, for regression analysis plotted in min)
R: Reaction time (corresponding TEG® parameter, in min)



MCF vs. MA

MCF: Maximum Clot Firmness (ROTEM® *delta* parameter, in mm))
MA: Maximum Amplitude (corresponding TEG® parameter, in mm)



Regression Statistics:

	n	Min ROTEM®/ TEG®	Max ROTEM®/ TEG®	Slope Deming	Intercept Deming	Slope OLS	Intercept OLS	R OLS
CT vs. R	100	1/0	6/6	0.99	0.29	0.94	0.35	0.9497
CFT vs. K	91	0/1	19/23	0.79	0.58	0.79	0.61	0.9855
α vs. Angle	100	10/34	88/87	1.47	-37.05	1.41	-32.91	0.9736
MCF vs. MA	93	15/3	80/78	0.87	6.76	0.85	7.89	0.9720

4.8.3 APTEM

Precision:

	CT CV (%)	CFT CV (%)	α-angle CV (%)	A20 CV (%)
Within-run[1]	7.8	7.3	2.2	2.7

[1] 5 runs on each of the 4 channels of one instrument testing healthy donor blood; CVs in highly pathological samples may vary

Heparin responsiveness:

When using ex-TEM® as an activator the parameters are unaffected up to a heparin concentration of 4 U/ml UFH in whole blood (corresponding to app. 8 U/ml in the plasma)

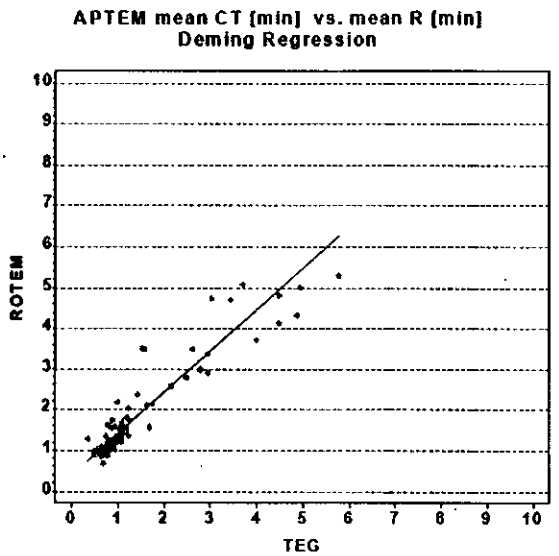
Method comparison with TEG® 5000 Thrombelastograph (Haemoscope Corp, Niles, IL):

Method comparison studies were conducted in 3 US centers on patient samples. The patients enrolled comprised patients during surgery and post surgery at the intensive care unit (ICU). In order to broaden the range of comparison, contrived samples were added.The extrinsically (ex-TEM®) activated APTEM test on ROTEM® *delta* was compared to an extrinsically activated tissue factor plus Trasysol® assay on TEG®5000.

Scatter Plots:

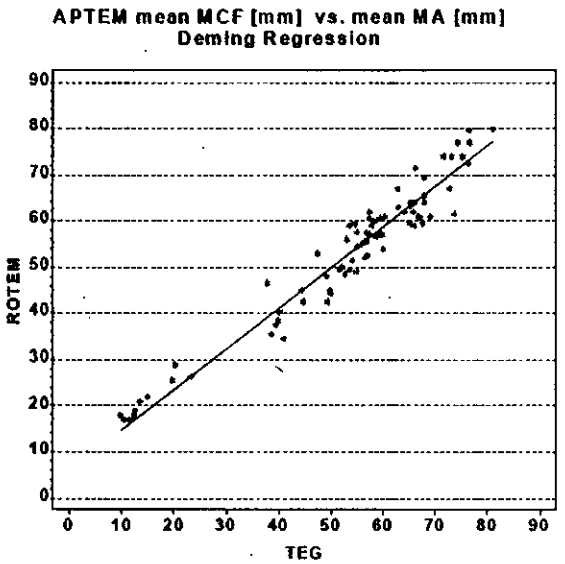
CT vs. R

CT: Clotting Time (ROTEM® *delta* parameter, usually in sec, for regression analysis plotted in min)
R: Reaction time (corresponding TEG® parameter, in min)



MCF vs. MA

MCF: Maximum Clot Firmness (ROTEM® *delta* parameter, in mm))
MA: Maximum Amplitude (corresponding TEG® parameter, in mm)



Regression Statistics:

	n	Min ROTEM®/ TEG®	Max ROTEM®/ TEG®	Slope Deming	Intercept Deming	Slope OLS	Intercept OLS	R OLS
CT vs. R	84	1/0	5/6	1.02	0.38	0.95	0.48	0.934
CFT vs. K	73	0/1	19/22	0.85	0.57	0.79	0.62	0.9757
α vs. Angle	82	10/36	88/87	1.51	-39.96	1.46	-37.39	0.9777
MCF vs. MA	79	17/10	80/81	0.88	5.84	0.86	7.05	0.9544

4.8.4 FIBTEM

Precision:

	A20 CV (%)
Within-run[1]	2.9

[1] 5 runs on each of the 4 channels of one instrument testing healthy donor blood; CVs in highly pathological samples may vary

Heparin responsiveness:

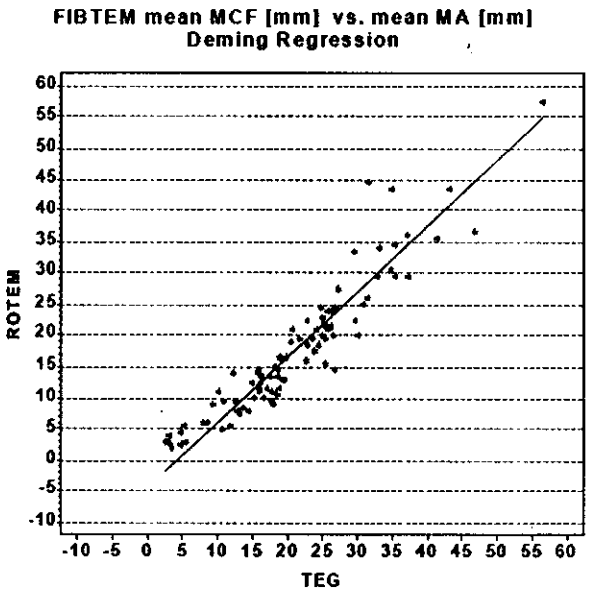
When using ex-TEM® as an activator the parameters are unaffected up to a heparin concentration of 4 U/ml UFH in whole blood (corresponding to app. 8 U/ml in the plasma)

Method comparison with TEG® 5000 Thrombelastograph (Haemoscope Corp, Niles, IL):

Method comparison studies were conducted in 3 US centers on patient samples. The patients enrolled comprised patients during surgery and post surgery at the intensive care unit (ICU).
In order to broaden the range of comparison, contrived samples were added.The extrinsically (ex-TEM®) activated FIBTEM test on ROTEM® *delta* was compared to an extrinsically activated tissue factor plus Reopro® assay on TEG®5000.

MCF vs. MA

MCF: Maximum Clot Firmness (ROTEM® *delta* parameter, in mm))
MA: Maximum Amplitude (corresponding TEG® parameter, in mm)



Regression Statistics:

	n	Min ROTEM®/ TEG®	Max ROTEM®/ TEG®	Slope Deming	Intercept Deming	Slope OLS	Intercept OLS	R OLS
MCF vs. MA	88	2/3	58/57	1.05	-4.53	0.98	-3.09	0.9384

4.9 Conclusion (Statement of Equivalence)

The data and information provided in this submission support a substantial equivalence determination, and, therefore, clearance of the 510(k) premarket notification for the EXTEM-, FIBTEM- and APTEM- assays on the ROTEM® *delta* Thromboelastometry System.

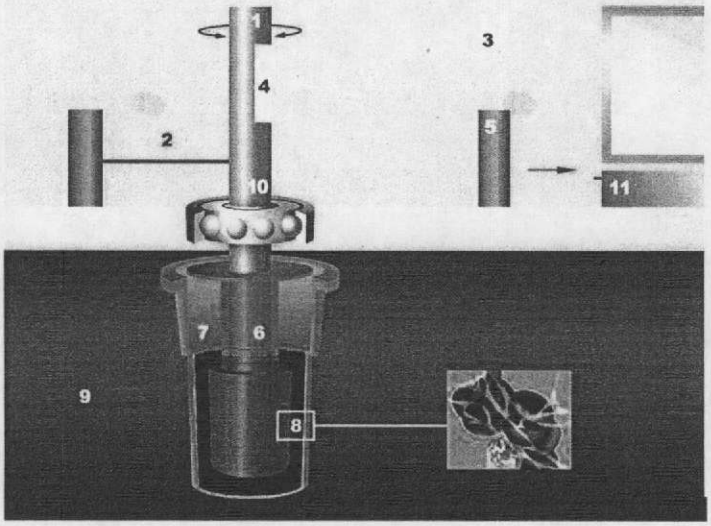
5.0 Device Description and Specifications

System Description

The previously cleared (K083842) ROTEM *delta* Thromboelastometry system is based on thromboelastometry, an improved form of the classical thromboelastography / thrombelastography developed by Hartert in 1948. The technique was previously called rotation thrombelastography (ROTEG®), but renamed in 2003*.

Thromboelastometry and thromboelastography are based on the measurement of elasticity of blood by continuous graphic logging of the firmness of a blood clot during clot formation (coagulation factors and inhibitors, platelets and fibrin) and subsequent fibrinolysis.

The ROTEM® Measurement Principle:
The patented ROTEM® technology is based on a disposable measurement cell with a fixed cup in which a pin oscillates permanently. The motion of the pin is detected by an optical detection system. Data are processed and analysed by a computer with special software.



1 oscillating axis (range 4,75°)
2 counterforce spring
3 light beam
4 mirror
5 CCD array (detector)
6 sensor pin
7 cup with blood sample
8 fibrin strands and platelet aggregates
9 temperature controlled cup holder
10 ball bearing
11 data processing unit

Fig. 1) ROTEM® measurement principle

* TEG® and Thrombelastograph® are trademarks of Haemoscope Corp./ TEM® and ROTEM® are registered trademarks of Tem Innovations GmbH

For measurement, the blood sample is filled into the 8 mm diameter cylindrical cup. This cup is placed on a 6 mm diameter pin which is attached to the lower end of a vertical axis. The centre section of the axis is guided by a ball bearing. The axis oscillates to the left and to the right by rotating through an angle of 4.75° via a s pring connector.

The rotation is detected optically via a mirror plate at the upper end of the axis, a diode as light source and a light sensitive sensor (CCD (charge-coupled device) array). If no clotting takes place, the movement is not obstructed. When a clot is formed and attaches itself to the pin and cup surfaces, the movement is obstructed.

The result is a balance between the torque introduced by the spring connector into the pin and the torque generated by the clot on the pin. As the clot becomes firmer, the rotational movement of the pin is reduced. The rotational movement of the pin is converted into amplitude with the following definitions applying to the ROTEM® *delta* analyzer:

ROTEM® Parameter	**Definition**	**Interpretation**
MCF Maximum Clot Firmness [mm]	Maximum clot firmness (maximum amplitude) of the developed clot during the test.	Normal/reduced/increased clot firmness.
A10, A20 Amplitude 10, 20 [mm]	Clot firmness (amplitude) at the time points 10 and 20 minutes after CT.	Normal/reduced/increased clot firmness.
CT Clotting Time [s]	The time from test start until first significant level of clot firmness (2 mm) is reached.	Normal/reduced/increased speed of coagulation initiation.
CFT Clot Formation Time [s]	The time from the CT/R until a clot firmness of 20 mm is reached.	Normal/reduced/increased speed of coagulation amplification and propagation (complementary parameter)
α Alpha Angle [°]	Angle between the baseline and a tangent to the clotting curve through the 2 mm (CT/R) point.	Normal/reduced/increased speed of coagulation amplification and propagation (complementary parameter)

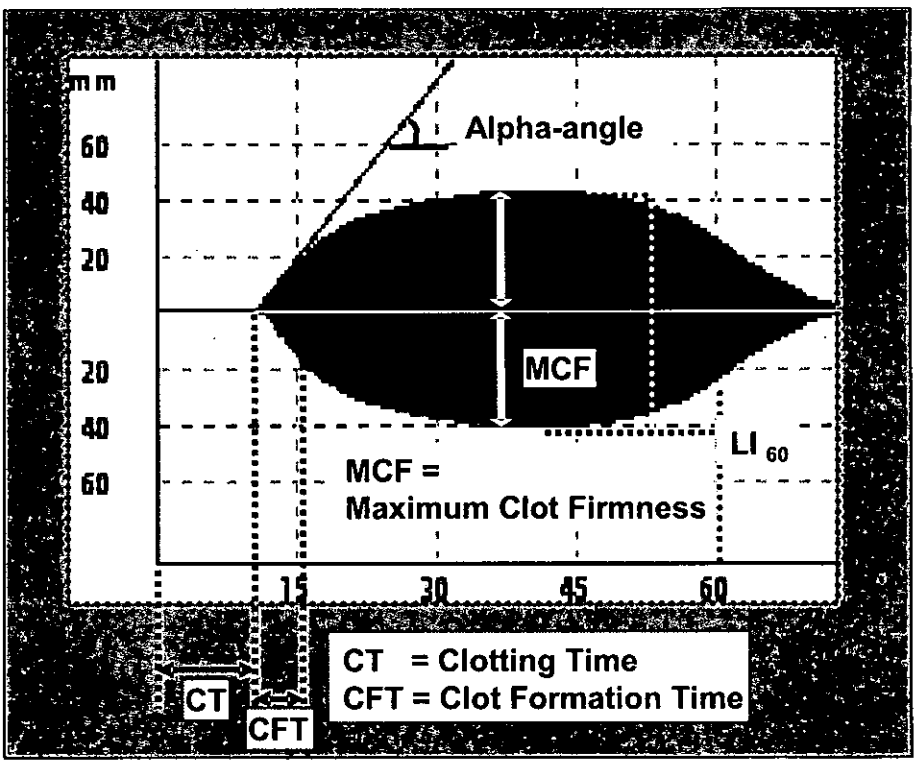


Fig. 2) The ROTEM® TEMogram and its Parameters

Amplitude of 0 mm means unobstructed rotation, while amplitude of 100 mm can be regarded as infinite firmness and blocking of the pin by the clot.
The result displayed on screen or printed out is called a "TEMogram" or "TEM".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Tem Innovations GmbH
c/o Dr. Volker-Joacham Friemert
Manager of Quality Managment and Regulatory Affairs
Martin-Kollar-Strasse 13-15
81829 Munich, Germany

AUG 1 0 2011

Re: k101533
Trade/Device Name: EXTEM® Assay, FIBTEM® Assay, APTEM® Assay for the ROTEM® *delta* 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: September 15, 2010
Received: September 21, 2010

Dear Dr. Friemert:

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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K101533

Device Name:
EXTEM assay

Indications for Use

The EXTEM assay is a semi-quantitative in vitro diagnostic assay on the ROTEM® *delta* Thromboelastometry System to monitor the coagulation process via the extrinsic 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)).
Speed of clot formation time (CFT and alpha) is complementary parameter and should be used only in conjunction with the main parameters Clotting time (CT) and Clot Firmness (A20/MCF).

The indication for ROTEM® *delta* use is in adult patients where 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 assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K101533

Indications for Use

510(k) Number: K101533

Device Name:
FIBTEM assay

Indications for Use

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 specimens after blocking platelet contribution to the clot firmness The fib-TEM® reagent is always used in conjunction with ex-TEM® reagent.

Clotting characteristics are described by the functional parameter Clot Firmness (A20/MCF).

The indication for ROTEM® *delta* use is in adult patients where 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 assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K101533

Indications for Use

510(k) Number: K101533

Device Name:
APTEM assay

Indications for Use

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 specimens after blocking hyperfibrinolysis by aprotinin. The ap-TEM® reagent is always used in conjunction with ex-TEM® reagent.

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)).
Speed of clot formation time (CFT and alpha) is complementary parameter and should be used only in conjunction with the main parameters Clotting time (CT) and Clot Firmness (A20/MCF).

The indication for ROTEM® *delta* use is in adult patients where 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 assess post-operative hemorrhage and / or thrombosis.

Prescription Use) ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K101533