



April 30, 2025

Haemonetics
Erica Molaro
Senior Regulatory Affairs Specialist
125 Summer Street
Boston, Massachusetts 02110

Re: K251024

Trade/Device Name: TEG 6s Hemostasis System Citrated: K, KH, RT, FF Assay Cartridge
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: April 2, 2025
Received: April 2, 2025

Dear Erica Molaro:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.

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

Indications for Use

510(k) Number (if known)

K251024

Device Name

TEG 6s Hemostasis System Citrated: K, KH, RT, FF Assay Cartridge

Indications for Use (Describe)

The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a 3.2% citrated whole blood sample. The Citrated: K, KH, RT, FF Assay Cartridge, to be used with the TEG 6s analyzer, contains four independent assays (CK, CKH, CRT, and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the TEG 6s System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the TEG 6s System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG 6s System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure. The TEG 6s Hemostasis System can be used in the laboratory or at the point-of-care.

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

Submitter: Haemonetics Corporation
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Contact: Erica Molaro
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Date Prepared: March 31, 2025

I. Device Information

Device Trade Name: TEG® 6s Hemostasis System: Citrated K, KH, RT, FF Assay Cartridge
Common Name: Whole Blood Hemostasis System
Classification Name: System, Multipurpose For In Vitro Coagulation Studies
Regulatory Class: 2
Regulation Number: 21 CFR 864.5425
Product Code: JPA

II. Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K243858	TEG 6s Hemostasis System Citrated: K, KH, RT, FF Assay Cartridge	JPA

III. Device Description Summary**TEG® 6s System Description**

The TEG® 6s Hemostasis System (TEG® Hemostasis analyzer and TEG® 6s Assay Cartridges) is intended for in vitro diagnostic use to provide semi-quantitative indications of a blood sample's ability to form and maintain a clot. The TEG® 6s Hemostasis System records the kinetic changes in a sample of whole blood as the sample clots, retracts and/or lyses. The system output consists of a table of numerical values and graphs resulting from the hemostasis process over time. This information can be used by clinicians to aid in determining if a clotting dysfunction or coagulopathy is present.

To perform a test, a disposable TEG® 6s Assay Cartridge is inserted into the TEG® 6s Hemostasis analyzer. The instrument reads the bar code on the cartridge and identifies the type of cartridge for operator confirmation. Blood (collected in a 3.2% sodium citrate tube) or Quality

Control (QC) material is added to the entry port on the cartridge and drawn into the cartridge under the TEG® 6s Hemostasis analyzer control. The amount of the sample drawn into the cartridge is determined by the pre-set volume of the blood chambers in the cartridge. Once in the cartridge, the sample is metered into as many as 4 separate analysis channels, depending upon the assays being performed. Reconstitution of reagents dried within the cartridge is accomplished by moving the sample back and forth through reagent chambers, under the control of microfluidic valves and bellows (pumps) within the cartridge. After each sample has been mixed with reagent, it is delivered to a test cell where it is monitored for viscoelastic changes due to coagulation. Excess sample material is moved under microfluidic control into an enclosed waste chamber within the cartridge.

TEG® 6s Measurement Technique

The TEG® 6s technology is based on a disposable cartridge containing up to 4 independent measurement cells. Each cell consists of a short vertically-oriented injection molded tube (ring). Detection of clotting in the TEG® 6s Hemostasis System is performed optically. A piezoelectric actuator vibrates the measurement cell(s) through a motion profile composed of summed sinusoids at different frequencies. The movement of the measurement cells will induce motion in the sample meniscus, which will be detected by a photodiode. The resulting motion of the meniscus is monitored optically and analyzed by the instrument to calculate the resonant frequency and modulus of elasticity (stiffness) of the sample. By performing a Fast Fourier Transform (FFT) on meniscus motion data, the resonant frequencies can be determined. The analyzer monitors the harmonic motion of a hanging drop of blood in response to external vibration. As the sample transitions from a liquid state to a gel-like state during clotting, the modulus of elasticity (stiffness) and therefore resonant frequency increase. The TEG® 6s Hemostasis analyzer measures these variations in resonant frequency during clotting and lysis.

Resonance is the tendency of a material or structure to oscillate with greater amplitude at some frequencies than others. The exact frequencies at which resonance occurs will depend on the stiffness and mass of the sample. Stiffness, in turn, is a function of a material's modulus of elasticity and the boundary conditions to which the material is exposed, such as the geometry and materials of a test cell. By holding these boundary conditions and sample mass constant from sample to sample, the TEG® 6s Hemostasis System allows direct comparison of elasticity between samples. The output measurements are displayed in a table and on a graphical tracing that reflects the hemostasis profile of the clot formation.

In a typical test, blood that has been delivered to the measurement cell will not clot for several minutes. During this time the sample has no inherent stiffness except that provided by surface tension, and since this remains constant the measured resonant frequencies will not change.

Once clotting begins, however, the elastic modulus and thus the resonant frequencies increase rapidly. During fibrinolysis, the process is reversed, with elastic modulus and resonant frequencies decreasing. In tests where clotting does not occur, the resonant frequency of the sample will not change. During coagulation, however, a clot will bind to the ring contained in the

cartridge and the resonant frequency will rise with increasing firmness of the clot. The TEG® 6s Hemostasis Analyzer collects meniscus motion data, tracks changing resonant frequencies and analyzes the frequency data to provide semi-quantitative parameters describing the clot.

The TEG® 6s Hemostasis System monitors the interaction of platelets within the fibrin mesh of the clot during clot formation and lysis, all in a whole-blood setting. The TEG® 6s Hemostasis System uses thromboelastography to provide continuous measurement of clot elasticity.

Table 1: TEG® 6s Parameters for TEG® 6s Citrated: K, KH, RT, FF Assay Cartridge

TEG 6s Parameter	Definition	Parameter Relation to Hemostasis
R	R is the time from the start of the test until initial fibrin formation. This represents the enzymatic portion of coagulation	Clotting time – Normal / reduced / increased speed of coagulation initiation
K	K is the time after R needed to reach a certain level of clot strength. This represents clot kinetics	Normal / reduced / increased speed of coagulation amplification and propagation
Alpha α (Angle)	Alpha is the angle representing the rate of increase in the clot strength the rapidity of fibrin build-up and cross-linking	Normal / reduced / increased speed of coagulation amplification and propagation
MA	MA, or Maximum Amplitude, represents the maximum firmness of the clot during the test.	Normal / reduced / increased clot elasticity/strength
FLEV	FLEV is an estimate of the fibrinogen level in the blood sample.	Estimated Functional Fibrinogen Level

Citrated Kaolin (CK) assay

The CK assay is a semi-quantitative in vitro diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG® 6s Hemostasis System. The CK assay consists of Kaolin which is used in the assay for activation of coagulation. It is combined with calcium chloride (CaCl₂) to neutralize the sodium citrate in the blood.

The clotting characteristics of the CK generated hemostasis profile are described by the functional parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot strength (MA). Since it may take an or more for a non-activated whole blood sample to reach maximum amplitude MA, Kaolin is essential to reduce run time and variability associated with running non-activated whole blood samples.

Citrated Kaolin with Heparinase (CKH) assay

The CKH assay is a semi-quantitative in vitro diagnostic assay for monitoring the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG® 6s

Hemostasis System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests. Calcium Chloride (CaCl_2) is included to neutralize any sodium citrate in the blood.

The CKH assay monitors the effects of heparin, a commonly used anticoagulant in surgical procedures. Even very low concentrations of heparin, fractions of IU/mL of blood, can noticeably increase the R time and can even completely anticoagulate the blood, making it difficult if not impossible to monitor developing coagulopathies that are masked by high levels of therapeutic heparin.

Citrated RapidTEG (CRT) assay

The CRT assay is a semi-quantitative in vitro diagnostic assay for monitoring the hemostasis process after stimulation of both the intrinsic and extrinsic pathway in 3.2% citrated whole blood specimens on the TEG® 6s Hemostasis System. The CRT assay consists of a reagent containing kaolin and tissue factor. It is combined with Calcium Chloride (CaCl_2) to neutralize sodium citrate in the blood sample. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA).

The CRT assay produces an accelerated clotting time which allows for an earlier MA results compared to the CK assay. Therefore, in the TEG® Hemostasis System, the CRT assay is simultaneously run along with the CK and CKH assays to provide a fast way to reach a stable value for MA (CRT) while still measuring the time- dependent parameters (CK).

Citrated Functional Fibrinogen (CFF) assay

The CFF assay is a semi-quantitative in vitro diagnostic assay for monitoring the hemostasis process after blocking platelet contributions to clot strength in 3.2% citrated whole blood specimens on the TEG® 6s Hemostasis System. The CFF assay consists of tissue factor and abciximab. It is combined with Calcium Chloride (CaCl_2) to neutralize sodium citrate in the blood sample.

Tissue Factor is used for coagulation activation that would be classically described as extrinsic, with platelet aggregation inhibited by abciximab (a GPIIb/IIIa inhibitor), excluding its contribution to clot strength, and thereby measuring fibrinogen contribution to clot strength. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA), the Estimated Functional Fibrinogen Level (FLEV).

IV. Intended Use/Indications for Use

The TEG 6s Hemostasis System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a 3.2% citrated whole blood sample. The Citrated: K, KH, RT, FF Assay Cartridge, to be used with the TEG 6s analyzer, contains four independent assays (CK, CKH, CRT, and CFF), described below.

The CK assay monitors the hemostasis process via the intrinsic pathway in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional

parameters Clotting Time (R), Speed of Clot Formation (K and Alpha angle) and Maximum Clot Strength (MA).

The CKH assay monitors the effects of heparin in 3.2% citrated whole blood specimens on the TEG 6s System. CKH is used in conjunction with CK, and heparin influence is determined by comparing Clotting Times (R) between the two tests.

The CRT assay monitors the hemostasis process via both the intrinsic and extrinsic pathways in 3.2% citrated whole blood specimens on the TEG 6s System. Clotting characteristics are described by the functional parameter Maximum Clot Strength (MA). The CRT MA parameter is equivalent to the CK MA parameter but the final MA value is reached more quickly using the CRT assay.

The CFF assay monitors hemostasis of 3.2% citrated whole blood specimens in the TEG 6s System after blocking platelet contributions to clot strength. Clotting characteristics are described by the functional parameters Maximum Clot Strength (MA) and the Estimated Functional Fibrinogen Level (FLEV).

Results from the TEG 6s analysis should not be the sole basis for a patient diagnosis, but should be evaluated together with the patient's medical history, the clinical picture and, if necessary, further hemostasis tests. The indication for TEG 6s System use is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure. The TEG 6s Hemostasis System can be used in the laboratory or at the point-of-care.

V. Comparison to Predicate Device

Indications for Use Comparison

The TEG® 6s system consists of the TEG® 6s analyzer including analyzer software and assay cartridges. The assay cartridges predicate device is the TEG® 6s Hemostasis System Citrated: K, KH, RT, FF (07-601-US; K243858). The indications for use are of the same intent with the following inclusion:

1. Addition of arterial whole blood as a sample matrix

Technology Comparison

There is no change to the technology, design of the device, reported parameters, or mechanics of how the cartridge is run on the TEG® 6s analyzer. No additional product development of the TEG® 6s system was required.

Table 2: Summary of Technological Characteristics for Substantial Equivalence: Similarities

	TEG® 6s Citrated: K, KH, RT, FF Cleared Device/Predicate [K243858]	TEG® 6s Citrated: K, KH, RT, FF Modified Device
Technological Purpose	Monitoring the physical response of a clot to low levels of applied strain (resonance frequency)	Same
Measurement	Changes in physical clot elasticity over time	Same
Initial Warm Up Time	5 minutes	Same
Analyzer Hardware	Fully integrated Thromboelastography analyzer	Same
Analyzer Measuring Technique	Non-contact optical measurement of shear elasticity of a coagulating sample	Same
Measurement Output	Graphical tracings of resonant frequency per reagent type; table of parameters	Same
Physical Configuration Used for Sample Measurement	Vertically-oriented cylindrical container (ring or tube) containing sample with meniscus formed at bottom; non-contact measurement of meniscus amplitude of vibration	Same
Physical Principle Underlying Measuring Technique	Clotting process causes an increase in the modulus of elasticity, which increases stiffness and increases the force of the clot within the ring walls when moving up and down in the ring tube against the sample's own weight. This increases the resonant frequency, which increases the clot strength amplitude. During clot dissolution (lysis), the resonant frequency decreases, corresponding to decreasing clot strength amplitude.	Same
Boundary Conditions	Physical ring tube dimensions define boundary conditions that are help constant, allowing comparison of one sample to the next.	Same
Measuring Channel	Up to 4	Same
Signal Generation	Multi-frequency harmonic oscillation of a small open-ended cylinder containing the sample	Same
Signal Transducer	Optical detection (silicon photodiode) of the motion of a free surface of the sample.	Same
Sensitivity to Applied Strains	Applied strains are very low, resulting in minimal interference with small changes in clot formation.	Same
Temperature Control	20° to 50°C	Same
Sample Volume (per channel)	20 µl	Same
Total Reaction Volume (single channel)	20 µl	Same
Mains Supply Voltage	100-240V, 50-60Hz (international power supply)	Same

	TEG® 6s Citrated: K, KH, RT, FF Cleared Device/Predicate [K243858]	TEG® 6s Citrated: K, KH, RT, FF Modified Device
Analyzer Input Voltage	12 volts DC, 60 watts max	Same
Environment	Stable and level surface. Operating Temperature 10° to 32° C Storage Temperature: -20° to +50° C (instrument only) Relative humidity 20 to 80% (noncondensing)	Same
Operating Position	Level (adjustment not required)	Same
Sample Preparation	Performed under analyzer control within the disposable cartridge	Same
Pipetting	Unmetered transfer pipette or syringe; blood sample is added until it fills to a level above the line marked on the blood intake well of the cartridge.	Same
Analyzer Software	Fully integrated Thromboelastography analyzer	Same
Consumables	Carrier (acrylic plastic) with microfluidics laminate and test rings (acrylic plastic)	Same
Assay	CK, CKH, CRT, CFF	Same
Assay Reagents	CK – kaolin and CaCl ₂ CKH – kaolin and CaCl ₂ with heparinase CRT – tissue factor, kaolin and CaCl ₂ CFF – abciximab (brand name ReoPro), tissue factor and CaCl ₂	Same
Assay Parameters Reported	CK: R, K, Angle, MA CKH: R CRT: MA CFF: MA, FLEV	Same
Quality Controls	Cartridge Reagent QC - Level 1 Cartridge Reagent QC - Level 2	Same
Use Location	Clinical laboratory or at the point-of- care.	Same

Table 3: Summary of Clinical Values Comparisons: Similarities

	TEG® 6s Citrated: K, KH, RT, FF Cleared Device/Predicate [K243858]	TEG® 6s Citrated: K, KH, RT, FF Modified Device
Clinical Values of Citrated: Kaolin (CK) Parameter R (min)	Initiation phase of coagulation triggered by enzymatic clotting factors and culminating with the initial fibrin formation. A prolonged R value is indicative of slow clot formation, due to coagulation factor deficiencies or heparin.	Same
Clinical Value of Citrated: Kaolin (CK) Parameter MA (mm)	MA, or Maximum Amplitude, Represents the maximum firmness of the clot during the test. The MA	Same

	TEG® 6s Citrated: K, KH, RT, FF Cleared Device/Predicate [K243858]	TEG® 6s Citrated: K, KH, RT, FF Modified Device
	provides information about the contribution of platelets/fibrin to the overall strength of the clot.	
Clinical Value of Citrated: Kaolin with Heparinase (CKH) Parameter R (min)	Initiation phase of coagulation triggered by enzymatic coagulation factors and culminating with the initial fibrin formation. A prolonged R value is indicative of slow clot formation, due to coagulation factor deficiencies or heparin. Inclusion of heparinase in the blood chamber channel of the cartridge provides ability to compare R (min) without the effect of heparin on the clot.	Same
Clinical Value of Citrated: RapidTEG Parameter MA (mm)	RapidTEG™ MA is the point at which clot strength reaches its maximum and reflects the end result of minimal platelet-fibrin interaction via the GPIIb/IIIa receptors. Due to faster coagulation activation, clot strength is measured faster than Citrated: Kaolin (K) activated samples. Same results as CK maximum amplitude (CK-MA). The MA provides information about the contribution of platelets/fibrin to the overall strength of the clot.	Same
Clinical Value of Citrated: Functional Fibrinogen Parameter MA (mm)	The maximum amplitude of CFF provides the functional fibrinogen contribution to the clot strength. Provides the overall contribution of functional fibrinogen to clot strength. In conjunction with CRT-MA, this assay enables an assessment of the relative contributions of functional fibrinogen and platelets to clot strength. Results may be valuable for guiding fibrinogen supplementation or platelet transfusion.	Same
Patient Population from Intended Use	Hemostasis evaluations are commonly used to assess clinical conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.	Same

Table 4: Summary of Technological Characteristics for Substantial Equivalence: Differences

	TEG® 6s Citrated: K, KH, RT, FF Cleared Device/Predicate [K243858]	TEG® 6s Citrated: K, KH, RT, FF Modified Device
Matrix	3.2% citrated venous whole blood	3.2% citrated whole blood (venous and arterial)

Non-Clinical Test Summary and Conclusions**Sample Matrix Equivalence**

Agreement analysis between TEG 6s and TEG 5000 by blood source from an observational study determined no statistical difference in agreement between TEG 6s and TEG 5000.

Agreement analysis between TEG 6s Citrated: K, KH, RT, FF and TEG 6s Citrated: K, KH, RTH, FFH determined the predicated bias met clinically acceptable bias limits across all parameters.

Conclusion

The information provided in this submission support a substantial equivalence determination for the TEG® 6s Hemostasis System: Citrated: K, KH, RT, FF and the predicate device.