



Food and Drug Administration
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April 19, 2017

Haemonetics Corporation
Mr. Brian Ciccariello
Manager, Regulatory Affairs
400 Wood Road
Braintree, MA 02184

Re: K160502

Trade/Device Name: TEG® 6s Hemostasis System; TEG Manager 2.0.0
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: April 03, 2017
Received: April 04, 2017

Dear Mr. Ciccariello:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Leonthena R. Carrington -S

Lea Carrington, MS, MBA, MT(ASCP)
Director
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Health
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Enclosure

Indications for Use

510(k) Number (if known)

K160502

Device Name

TEG 6s Hemostasis System

Indications for Use (Describe)

The TEG 6s System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The TEG 6s System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV. The TEG 6s System provides specific blood modifiers, in the form of reagents dried-in-place within TEG 6s cartridges.

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 use for the TEG 6s System 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.

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:

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Contact:

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Device Information:

Trade Name: TEG 6s Hemostasis System
Common Name: Whole Blood Hemostasis System
Classification Name: Multipurpose System for in vitro Coagulation Studies
Regulation Number: 21 CFR 864. 5425
Product Code: JPA
Device Class: II

Predicate Device

Trade Name: TEG 6s Hemostasis System 510(k) K140893 clearance Date Jan 3, 2015
TEG 6s Hemostasis System 510(k) K150041 clearance Date June 26, 2015

Device Characteristics Summary:

The TEG6s analyzer is a four-channel in vitro diagnostic instrument with an integrated computer module, a display touch screen for operator interaction, and a slot for inserting one TEG 6s cartridge. The TEG 6s analyzer is for use in laboratories and near patient use. It consists of an assembly of controllers, sensors, and displays, all managed and sequenced by a central processor. The embedded programming in the processor provides the necessary information for the automation of hemostasis testing. The program sequences the instrument hardware through the appropriate cycles to perform the test. Using a compressor, pressure and vacuum

sensors, and a series of valves, actuators and controls, blood samples are introduced into the microfluidics of a disposable cartridge.

To perform a test, a disposable cartridge is inserted into the instrument. The instrument reads the bar code on the cartridge, identifies the type of cartridge for operator confirmation. Then, the operator adds a blood sample to the entry port on the cartridge and uses the touch screen to issue the command to the instrument to proceed with the test. The sample is then drawn into the cartridge under instrument control. The amount of the sample drawn into the cartridge is automatically determined by the volume of the reagent chambers in the cartridge.

The TEG 6s analyzer firmware provides features for and manages all functions of the instrument, including user interface (via the touch display screen) and external communications for service and installation via Service Maintenance Software (SMS). SMS is run on a separate computer connected to one or more TEG 6s analyzer(s) via the Ethernet port and a router. Its purpose is to allow additional control of analyzer functions by authorized remote users, such as administrative and service personnel.

The TEG Manager 2.0.0 is an optional accessory to Haemonetics TEG 6s Hemostasis System. TEG Manager 2.0.0 is an application that provides remote viewing of current and historical patient tracing and test results created by the TEG 6s analyzers, and administration of all connected TEG 6s devices. TEG Manager interfaces with the TEG analyzers to obtain clinical data and retrieves patient information from external Hospital Information System (HIS). Users cannot manipulate the data that is stored and displayed within TEG Manager or input any additional clinical data in the software.

Intended Use and Indications for Use:

Please refer to the Comparison Table below for Intended Use and Indications for Use.

Non-Clinical Testing Summary:

The TEG Manager 2.0.0 software was thoroughly verified and validated via test standards. The overall approach to testing was to test the software at different levels, including unit, system/integration, verification, validation and beta testing. The acceptance criteria for verification and validation testing were identified in the individual test cases as the expected results. Test cases were comprised of scenarios with multiple steps along with their respective expected results. When all the steps were tested and the actual results matched the expected

results, the test case result was passed. Test data demonstrated that the device met all acceptance requirements, and that the subject device is as safe, as effective, and performs as well as or better than the predicate device.

Substantial Equivalence:

TEG 6s Analyzer with TEG Manager as an optional accessory is substantially equivalent to the 510(k) cleared (K150041) TEG 6s Analyzer. TEG Manager 2.0.0 is intended to be used as an optional accessory with the TEG 6s Analyzer as a remote viewer of the data provided by the TEG 6s analyzer. TEG Manager 2.0.0 does not provide any additional analytical or interpretive data outside of the TEG analyzer capabilities.

TEG Manager 2.0.0 allows users to edit non clinical patient information data, add notes, and provide email capability that is currently on the TEG 6s analyzer, from a remote location, as long as TEG Manager 2.0.0 is connected to the analyzer. TEG Patient information edits have no impact on the hospital's HIS and do not affect clinical data. The addition of TEG Manager 2.0.0 as an optional accessory to the TEG 6s Analyzer does not render the device non-substantially equivalent because non-clinical testing has demonstrated that the subject device is as safe and effective as the predicate and the results of verification and validation have not raised different questions of safety and effectiveness than the predicate.

Table 1: Comparison of the TEG 6s Analyzer with TEG Manager to Predicate TEG 6s Analyzer

	Predicate TEG 6s Analyzer (K140893 & K150041)	Subject TEG 6s Analyzer with TEG Manager
Manufacturer	Haemonetics Corporation	Same
Trade Name	TEG 6s Hemostasis System	TEG 6s Hemostasis System
Common Name	Whole Blood Hemostasis System	Same
Classification Name	Multipurpose System for in vitro Coagulation Studies (K150041) Automated platelet aggregation system (K140893)	Same as (K150041)
Regulation Number	21 CFR 864. 5425 (K150041) 21 CFR 864.5700 (K140893)	Same as (K150041)
Product Code	JPA (K150041) JOZ (K140893)	Same as (K150041)
Device Class	II	Same
Indications for Use	<p>The TEG 6s System is intended for in vitro diagnostic use to provide semi-quantitative indications of the hemostasis state of a blood sample. The TEG 6s System records the kinetic changes in a venous sample of 3.2% citrated whole blood as the sample clots, and retracts in real time. The system output consists of a table of numerical values for parameters R, K, Angle, MA, and FLEV.</p> <p>The TEG 6s System provides specific blood modifiers, in the form of reagents dried-in-place within TEG 6s cartridges.</p> <p>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.</p> <p>The indication for use for the TEG 6s System is with adult patients where an evaluation of their blood hemostasis properties is desired. Hemostasis evaluations are commonly used to assess clinical</p>	Same



	Predicate TEG 6s Analyzer (K140893 & K150041)	Subject TEG 6s Analyzer with TEG Manager
	conditions in cardiovascular surgery and cardiology procedures to assess hemorrhage or thrombosis conditions before, during and following the procedure.	
Intended use	Same as Indications for Use	Same
Disposables	Citrated Multichannel Cartridge PlateletMapping Assay Cartridges Abnormal Wet Quality Control Material	Same
Analyzer Software	Analyzer has fully integrated Thrombelastography software	Same TEG Manager 2.0.0. is an optional accessory to be used with the TEG System. TEG Manager provides remote viewing of current and historical test results created by the TEG System.
Analyzer Hardware	Analyzer	Same

Conclusion:

The data and information provided in the submission support a substantial equivalence determination for the TEG 6s Analyzer and the proposed TEG 6s Analyzer with TEG Manager as an optional accessory.