March 27, 2024

HemoSonics LLC
Deborah Winegar
Vice-President, Clinical Affairs
4020 Stirrup Creek Drive
Suite 105
Durham, North Carolina 27703

Re: K240045
Trade/Device Name: QStat Cartridge
Regulation Number: 21 CFR 864.5430
Regulation Name: Coagulation System For The Measurement Of Whole Blood Viscoelastic Properties In Perioperative Patients
Regulatory Class: Class II
Product Code: QFR
Dated: March 19, 2024
Received: March 19, 2024

Dear Deborah Winegar:

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.

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

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.

Submission Number *(if known)*

K240045

Device Name

QStat Cartridge

Indications for Use *(Describe)*

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous or arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.

The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.

Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.

For prescription 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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SPECIAL 510(K) SUMMARY

APPLICANT INFORMATION

Submission Date: January 2024

Submitter Information: HemoSonics, LLC
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Durham, NC 27703
Phone: 919-244-6990

Contact Person: Deborah Winegar, PhD
Email: dwinegar@hemosonics.com
Phone: 919-244-6990

PROPRIETARY AND ESTABLISHED NAMES

QStat® Cartridge

REGULATORY INFORMATION

Trade/Device Name:	QStat Cartridge
Regulation Number:	21 CFR 864.5430
Regulation Name:	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients
Regulatory Classification:	Class II
Product Code:	QFR

PURPOSE OF SUBMISSION

To add a sample matrix to the intended use and indications for use statement for the QStat Cartridge. This change does not alter the device's fundamental scientific technology.

MEASURAND

The combination of clot time and clot stiffness parameters measured from the four channels of the cartridge provides information about the functional role of coagulation factors, fibrinogen, and platelets in the sample.

TYPE OF TEST

The QStat Cartridge is an in vitro diagnostic device used with the Quantra Hemostasis Analyzer to assess a patient's coagulation system by measuring the viscoelastic properties of a blood sample during clot formation and clot lysis. The QStat Cartridge is used with the Quantra Hemostasis Analyzer (instrument) and QStat Controls (external Quality Control materials).

INTENDED USE AND INDICATIONS FOR USE STATEMENT

The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous or arterial whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics.

The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL).

The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.

Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis.

For prescription use only.

DEVICE DESCRIPTION

The QStat Cartridge is a single-use, multi-channel disposable plastic cartridge used with the Quantra Hemostasis Analyzer for the evaluation of blood coagulation and clot lysis. The measurements are performed in four test channels of the disposable cartridge which enable differential testing with different sets of reagents without the need for any reagent preparation or controlled pipetting. The cartridge utilizes a citrated evacuated blood collection tube filled with a patient whole blood sample The proprietary technology SEER Sonorheometry measures the evolution of shear modulus (i.e., clot stiffness) in all four channels as a function of time. The QStat Cartridge is intended for use in patients 18 years or older by professionals in a hospital setting (point of care or laboratory) to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures.

Each QStat Cartridge is pre-filled with lyophilized reagent beads individually sealed in an airtight pouch. After a QStat Cartridge is removed from its primary packaging, it is inserted into the instrument dock. A whole blood sample, collected in a 3.2% sodium citrate anticoagulant blood collection tube (minimum volume 2.7 mL), is attached directly to the cartridge and the test is initiated using the touch screen interface on the Quantra Hemostasis Analyzer. The cartridge is the only component of the Quantra System that is in direct contact with blood. The fluidic system within the instrument draws the sample into the cartridge where it is warmed to 37°C, aliquoted, introduced and mixed with the lyophilized reagents, and analyzed. When the test is complete, the cartridge is released from the dock to be disposed of in an appropriate biosafety sharps container.

Table 1 summarizes the lyophilized reagents contained in each cartridge channel of the QStat Cartridge and the output parameter reported. Clot times and clot stiffness values obtained from the measurements performed by the QStat Cartridge are combined to form parameters that depict the functional status of the patient's coagulation system. Four (4) of the parameters are measured and two (2) are calculated. The assay provides the following information for each patient sample: Clot Time (CT), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS) and Clot Stability to Lysis (CSL).

Table 1. QStat Cartridge Output Parameters

Channel	Reagents	QStat Cartridge Output Parameter (units of measure)
1	Kaolin, calcium buffers &stabilizers	Clot Time (CT) (seconds)
2	Thromboplastin, tranexamic acid (TXA), polybrene, calcium, buffers, and stabilizers	No direct output (see calculated parameters)
3	Thromboplastin, polybrene, calcium, buffers & stabilizers	Clot Stiffness (CS) (hectoPascals)
4	Thromboplastin, polybrene, abciximab, calcium, buffers & stabilizers	Fibrinogen Contribution (FCS) (hectoPascals)
Calculated Parameters		
2&3	See above	Clot Stability to Lysis (CSL) (percent)
3&4	See above	Platelet Contribution to Clot Stiffness (PCS) (hectoPascals)

The analyzer displays the test results (n=5) in three different views: dial display screen, stiffness curves data, and trend screen. The dial display screen is the primary viewing screen and has a dial for each of the five output parameters. Each dial shows the reference range, assay measurement range, parameter abbreviation, and the numerical result for the corresponding parameter. The stiffness curves are a graphical display of shear modulus measurements over time that enable the user to view the development of clot stiffness over time. The trends screen displays results from a patient for up to six time points.

There are two levels of external QStat Controls (QSL1 and QSL2) that are supplied separately (required but not provided materials) for testing on the Quantra System when changing cartridge lots, changing control lots, or after significant changes are made to the Quantra instrument (e.g., software update).

DEVICE MODIFICATION DESCRIPTION

The QStat Cartridge was previously cleared under K213917 with a sample matrix claim of venous whole blood. HemoSonics is submitting this Special 510(k) to demonstrate the equivalency of arterial and venous whole blood samples analyzed on the Quantra Hemostasis Analyzer with the QStat Cartridge in order to expand the sample matrices accepted on this system.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name: QStat Cartridge

Predicate 510(k) Number: K213917

Comparison with the Predicate:

Table 2 provides an overall comparison of the modified QStat Cartridge with the previously cleared QStat Cartridge.

Table 2: Comparison between K213917 and Modified QStat Cartridge

	Modified Device	**Predicate Device**
	QStat Cartridge (Subject of Special 510(k))	**QStat Cartridge (K213917)**
Similarities		
Manufacturer	HemoSonics, LLC	Same
Trade Name	QStat Cartridge	Same
Common Name	Whole Blood Hemostasis System	Same
Classification Name	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients	Same
Regulation Number	21 CFR 864.5430	Same
Product Code	QFR	Same
Device Class	II	Same
Location of Use	Point of care and laboratory settings	Same
Disposables	QStat Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)	Same
Analyzer Hardware	Quantra Hemostasis Analyzer HS-002	Same
Differences		
Indications for use	The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous **or arterial** whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot	The QStat Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation and clot lysis state of a 3.2% citrated venous whole blood sample using the Quantra Hemostasis Analyzer. The QStat Cartridge includes tests to assess coagulation via the intrinsic and extrinsic pathways and includes a test with tranexamic acid to evaluate clot lysis characteristics. The QStat Cartridge is intended for in vitro diagnostic use by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood by means of the following functional parameters: Clot Time (CT), Clot

	Modified Device	Predicate Device
	QStat Cartridge (Subject of Special 510(k))	**QStat Cartridge (K213917)**
	Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL). The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures. Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis. For prescription use only.	Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS), and Clot Stability to Lysis (CSL). The QStat Cartridge is indicated for the evaluation of blood coagulation and clot lysis in patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in trauma and liver transplantation procedures. Results obtained with the QStat Cartridge should not be the sole basis for patient diagnosis. For prescription use only.
Sample Type(s)	Arterial and venous whole blood	Venous whole blood
Analyzer Software	Ver 2.4.1 (cleared in K232215)	Ver 2.0.36