December 13, 2022

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

Re: K223433
Trade/Device Name: Quantra QPlus System
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: November 14, 2022
Received: November 14, 2022

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 (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 -S

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)*

Device Name
QPlus® Cartridge

Indications for Use *(Describe)*

The Quantra® QPlus® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra QPlus System is intended for in vitro diagnostic use.

The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The QPlus Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation state of a 3.2% citrated venous or arterial whole blood sample. The QPlus Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer.

The system is intended to be used 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 Time with Heparinase (CTH), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS) and Clot Time Ratio (CTR).

The Quantra QPlus System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure. Results obtained with the Quantra QPlus System should not be the sole basis for patient diagnosis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. SPECIAL 510(K) SUMMARY

A. APPLICANT INFORMATION

Submission Date: November 14, 2022

Submitter Information:
HemoSonics, LLC
4020 Stirrup Creek Drive, Suite 105
Durham, NC 27703
Phone: 919-244-6990

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

B. PROPRIETARY AND ESTABLISHED NAMES

Quantra® QPlus® System

C. REGULATORY INFORMATION

Trade/Device Name:	Quantra QPlus System
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

D. PURPOSE OF SUBMISSION

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

E. 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.

F. TYPE OF TEST

The Quantra QPlus System is an in vitro diagnostic device designed to assess a patient's coagulation system by measuring the viscoelastic properties of a blood sample during clot formation in surgical and intensive care settings. The system consists of the Quantra Hemostasis Analyzer (instrument), a single-use disposable cartridge, (QPlus Cartridge) and Quantra Quality Controls (external Quality Control materials).

G. INTENDED USE AND INDICATIONS FOR USE STATEMENT

The Quantra® QPlus® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra QPlus System is intended for *in vitro* diagnostic use.

The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The QPlus Cartridge is a multi-channel cartridge that provides semi-quantitative indications of the coagulation state of a 3.2% citrated venous or arterial whole blood sample. The QPlus Cartridge includes tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer.

The system is intended to be used 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 Time with Heparinase (CTH), Clot Stiffness (CS), Fibrinogen Contribution to Clot Stiffness (FCS), Platelet Contribution to Clot Stiffness (PCS) and Clot Time Ratio (CTR).

The Quantra QPlus System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure. Results obtained with the Quantra QPlus System should not be the sole basis for patient diagnosis.

H. DEVICE DESCRIPTION

The Quantra QPlus System consists of an instrument (the Quantra Hemostasis Analyzer), a single-use disposable cartridge (QPlus Cartridge), and external quality control materials (QPlus Controls). The QPlus System is intended for use with patients 18 years or older by professionals in a hospital setting (point of care or laboratory). The measurements are performed in four test channels of the disposable cartridge.

The QPlus Cartridge is a multichannel disposable cartridge which enables four independent measurements to be performed in parallel 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.

Clot times and clot stiffness values obtained from the measurements performed by the QPlus 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 parameters are summarized in **Table 5-1**.

Table 5-1. QPlus Cartridge Output Parameters

Channel	Reagents	Measurement	Description	Units	Reportable Range
1	Kaolin, calcium buffers &stabilizers	Clot Time (CT)	Clot time in citrated whole blood	sec	60 to 480
2	Kaolin, heparinase I, calcium buffers & stabilizers	Heparinase Clot Time (CTH)	Clot time in citrated whole blood with heparin neutralization	sec	60 to 480
3	Thromboplastin, polybrene, calcium, buffers & stabilizers	Clot Stiffness (CS)	Stiffness of the whole blood clot	hPa (hectopascals)	2 to 65
4	Thromboplastin, polybrene, abciximab, calcium, buffers & stabilizers	Fibrinogen Contribution (FCS)	Contribution of functional fibrinogen to clot stiffness	hPa (hectopascals)	0.2 to 30
Calculated	Calculated by subtracting FCS from CS	Platelet Contribution (PCS)	Contribution of platelet activity to clot stiffness	hPa (hectopascals)	2 to 50
Calculated	Calculated ratio of CT over CTH	Clot Time Ratio (CTR)	Assessment of residual heparin anticoagulation	Unitless	0.8 to 4

I. DEVICE MODIFICATION DESCRIPTION

The Quantra System was previously cleared under DEN180017 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 QPlus Cartridge in order to expand the sample matrices accepted on this system.

J. SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name: Quantra Plus System

Predicate 510(k) Number: DEN180017

Comparison with the Predicate:

Table 5-2 provides an overall comparison of the modified Quantra QPlus System with the previously cleared Quantra QPlus System.

Table 5-2: Comparison between DEN180017 and Modified Quantra System

	Modified Device	Predicate Device
	Quantra System (Subject of Special 510(k))	**Quantra System (DEN180017)**
Similarities		
Manufacturer	HemoSonics, LLC	Same
Trade Name	Quantra QPlus System	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	QPlus Cartridge (multichannel cartridge) QStat Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)	Same
Analyzer Hardware	Quantra Hemostasis Analyzer HS-002	Same
Analyzer Software	Ver 2.1.37	Same
Differences		
Indications for use	The Quantra® QPlus® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, QStat Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra System is intended for in vitro diagnostic use. The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The cartridges are multi-channel and provides semi-quantitative indications of the coagulation state of a	The Quantra® QPlus® System is composed of the Quantra Hemostasis Analyzer, QPlus Cartridge, QStat Cartridge, and Quantra Quality Controls Level 1 and 2. The Quantra System is intended for in vitro diagnostic use. The Quantra Hemostasis Analyzer uses Sonic Estimation of Elasticity via Resonance (SEER) Sonorheometry, an ultrasound-based technology, to measure the shear modulus of whole blood during coagulation. The cartridges are multi-channel and provides semi-quantitative indications of the coagulation state of a

	Modified Device	Predicate Device
	Quantra System (Subject of Special 510(k))	**Quantra System (DEN180017)**
	3.2% citrated venous or arterial whole blood sample. Cartridges include tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer. The system is intended to be used by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood. The Quantra System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure. Results obtained with the Quantra System should not be the sole basis for patient diagnosis.	3.2% citrated venous whole blood sample. Cartridges include tests to assess coagulation characteristics via the intrinsic pathway, via the extrinsic pathway, and includes tests with a heparin neutralizer. The system is intended to be used by trained professionals at the point-of-care and in clinical laboratories to evaluate the viscoelastic properties of whole blood. The Quantra System is indicated for the evaluation of blood coagulation in perioperative patients age 18 years and older to assess possible hypocoagulable and hypercoagulable conditions in cardiovascular or major orthopedic surgeries before, during, and following the procedure. Results obtained with the Quantra System should not be the sole basis for patient diagnosis.
Sample Type(s)	Arterial and venous whole blood	Venous whole blood