August 21, 2020

HemoSonics, LLC
Anne Zavertnik
Vice President, Regulatory Affairs and Quality Systems
400 Preston Avenue, Suite 250
Charlottesville, Virginia 22903

Re: K201513
Trade/Device Name: Quantra QPlus System
Regulation Number: 21 CFR 864.5430
Regulation Name: Coagulation system for the measurement of whole blood viscoelastic properties
Regulatory Class: Class II
Product Code: QFR
Dated: June 5, 2020
Received: June 8, 2020

Dear Anne Zavertnik:

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,

Takeesha Taylor-Bell
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K201513

Device Name
Quantra QPlus System

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 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.

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510(K) SUMMARY

A. APPLICANT INFORMATION

Submitter Information:
HemoSonics, LLC
400 Preston Avenue, Suite 250
Charlottesville, VA 22903
Phone: 434-202-1032

Contact Person:
Anne Zavertnik, RAC
Email: azavertnik@hemosonics.com
Phone 434-202-1032 x100, 585-500-8427 mobile

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 implement an optional accessory to the Quantra QPlus System called the Quantra® Desktop Remote Viewer software application. This change does not affect the device's intended use nor 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), QPlus Cartridge (single-use disposable cartridge) and Quantra Quality Controls (external Quality Control materials).

G. INTENDED USE/INDICATIONS FOR USE

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 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 MODIFICATION DESCRIPTION

The Quantra QPlus System was previously cleared under DEN180017. HemoSonics is submitting this Special 510(k) to implement a software modification to the Quantra Hemostasis Analyzer that allows an optional accessory, Quantra Desktop Remote Viewer (QDRV), for viewing results from a location separate from the Quantra. The QDRV is a PC based software application that allows remote viewing of real-time (active) and historical test results created by the Quantra Hemostasis Analyzer only by authorized users. Users cannot manipulate the test data that is stored on the Quantra Hemostasis Analyzer and displayed within the QDRV software application. Users cannot input any additional clinical data into the QDRV software application or the Quantra Hemostasis Analyzer from the QDRV.

I. SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name: Quantra Plus System

Predicate 510(k) Number: DEN180017

Comparison with the Predicate:

Table 5-1 provides an overall comparison of the modified Quantra QPlus System with the previously cleared Quantra QPlus System.

Table 5-1: Comparison between Quantra QPlus System (DEN180017) and Modified Quantra QPlus System

	Modified Device	Predicate Device
	Quantra QPlus System (Subject of Special 510(k))	**Quantra QPlus System (DEN180017)**
Similarities		
Manufacturer	Same as predicate device	HemoSonics, LLC
Trade Name	Same as predicate device	Quantra Hemostasis Analyzer
Common Name	Same as predicate device	Whole Blood Hemostasis System
Classification Name	Same as predicate device	Coagulation system for the measurement of whole blood viscoelastic properties in perioperative patients.
Regulation Number	Same as predicate device	21 CFR 864.5430
Product Code	Same as predicate device	QFR (DEN180017)
Device Class	Same as predicate device	II
Indications for Use	Same as predicate device	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 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.
Intended Use	Same as predicate device	Same as indications for use
Disposables	Same as predicate device	QPlus Cartridge (multichannel cartridge) Quantra Quality Controls (Level 1 and Level 2)
Analyzer Hardware	Same as predicate device	Quantra Hemostasis Analyzer HS-002
Differences		
Quantra Hemostasis Analyzer Software	v1.10.6	v.1.6.15
Quantra Desktop Remote Viewer	Optional software application v2.1.15	Not Applicable

Conclusion:

The data and information provided in the submission support the substantial equivalence determination for the Quantra QPlus System with optional QDRV to the Quantra QPlus System approved in DEN180017.