DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 20, 2015

Diagnostica Stago, Inc.
James Monroe
Regulatory Project Manager
5 Century Drive
Parsippany, NJ 07054

Re: K151867
Trade/Device Name: STA R Max®
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: June 29, 2015
Received: July 10, 2015

Dear Mr. Monroe:

This letter corrects our substantially equivalent letter of August 7, 2015.

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 Parts 801 and 809), 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 yours,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
STA R Max®

Indications for Use *(Describe)*
The STA R Max® is a fully automatic clinical instrument designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

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.

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"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."

Attachment_09

510(k) Summary

STA R Max®

A. 510(k) Submitter information

Submitter's name	Diagnostica STAGO S.A.S
Address	125 Avenue Louis Roche 92230 Gennevilliers France
Phone Number	+33 1 46 85 48 80
Fax Number	+33 1 41 47 57 50
Date of Preparation	06/29/2015

Application Correspondent and Contact Person information

Name	James Monroe
Address	5 Century Drive Parsippany, New Jersey 07054
Phone Number	+1-973-631-1200 x 4306
Fax Number	+1-973-775-8063

B. Device Information

Device Trade Name	STA R Max®.
Device Common Name	IVD Coagulation Device/Instrument Automated and Semi-Automated Hematology device Multi-Parametric Analyzer
Device Classification Name	System, Multipurpose for In Vitro Coagulation Studies
Regulatory Class	Class II
Panel	Part 864 - Hematology and Pathology Devices
Product Code	JPA
Regulation Number	864.5425

Picture 1: STA R Max®

C. Predicate Device Information

510(k) Number	K093001
Device Trade Name	STA-R Evolution® Expert Series
Device Common Name	STA-R Evolution® Expert Series IVD Coagulation Device/Instrument Automated and Semi-Automated Hematology device Multi-Parametric Analyzer
Device Classification Name	System, Multipurpose for In Vitro Coagulation Studies
Regulatory Class	Class II
Panel	Part 864 - Hematology and Pathology Devices
Product Code	JPA
Regulation Number	864.5425

Picture 2: STA-R Evolution® Expert Series (K093001)

D. Indication/Intended Use

The STA R Max® is a fully automatic clinical instrument designed to perform tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.

E. Purpose of the Special 510(k) Notice

The STA R Max® is a modification to the company's own legally marketed device, STA-R Evolution® Expert Series (K093001).

The modifications of the device involve:

-1- Implementation of a new graphical user interface (GUI) to use the graphical chart of Max line of STA Analyzers.

-2- Changes to the external design (colors and shape) of the analyzer which include modifications of the openings and the addition of a new computer table for improved ergonomics.

-3- Improvement of the communication protocol with a LIS or a middleware so more information can be exchanged.

F. Description of the device

Diagnostica Stago's STA R Max® is a fully automatic clinical laboratory designed as a modification to the company's previously cleared STA-R Evolution® Expert Series analyzer (K093001). It performs tests which aid in the diagnosis of Haemostatic disorders and the monitoring of anticoagulant treatment.

The device consists of the following components:

-1- a cuvette, which holds the patient sample and any needed reagent;

-2- a metal ball located in the cuvette, that is induced to oscillate to measure coagulation;

-3- three needles that will aspirate and dispense the patient's sample and reagents into the cuvette;

-4- oscillation amplitude detection of a metal ball in a cuvette to measure sample coagulation by the chronometric method;

-5- a light source and sensor to transmit light through the cuvette containing the sample and reagents that subsequently measures the light absorbed as a reaction takes place;

-6- Software which conducts the measurement and test determination;

1) Principles of Operation

The principles of operation are the same as described for STA –R Evolution® Expert Series (predicate device) in submission, K093001. A brief summary follows:

- The STA R Max® is designed as a fully automatic system. Samples and test reagents are loaded into the instrument where sample handling, reagent delivery, analysis, and reporting of results are performed automatically. A central processing unit controls instrument functions such as, management of patient results, quality control, system supervision, support for instrument maintenance, and workload optimization.
- The instrument utilizes Diagnostica Stago reagents in addition to open adaptation of other currently available reagents. Barcoding of test reagents, calibrators and controls

facilitate their use on the system and facilitates reagent management. Manual entry of reagent information enables the use of non-barcoded-reagents.

- There are two methods used by the instrument to measure coagulation: the chronometric (clotting time or clot-based measurements) and photometric assays (at specific wave lengths) on plasma samples.

2) Fundamental technologies

The Technological characteristics are the same for the STA R Max® and the STA-R Evolution® Expert Series

- Chronometry Measurement Principle

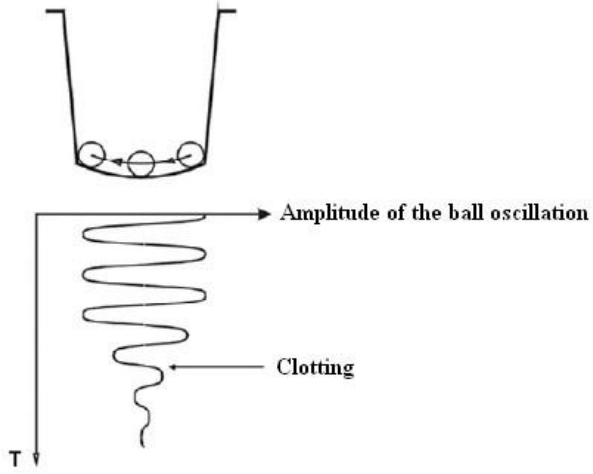
The principle consists in measuring the variations of the ball oscillation amplitude through inductive sensors. The ball has a pendular movement obtained:

- due to the two curved rail tracks in the bottom of the cuvettes
- and an alternating electromagnetic field generated by two independent drive coils.

The oscillation amplitude is constant when the viscosity of the medium through which the ball moves remains constant.

The oscillation amplitude decreases when the viscosity of this medium increases as shown in Schema 1.

Schema 1: Amplitude of the ball oscillation during clotting

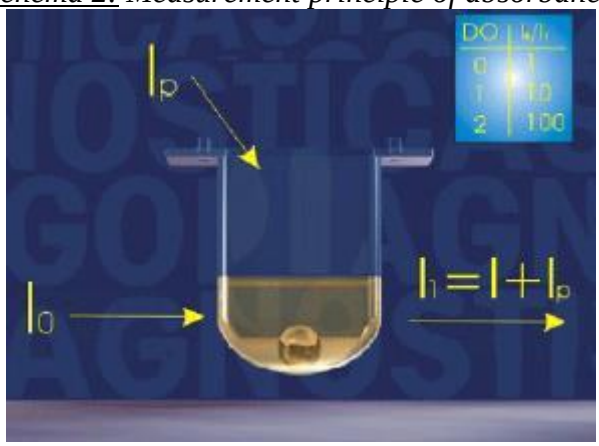


- Photometry Measurement Principle

The detection principle for chromogenic or immunological analyses on the STA R Max® is based on the absorbance (optical density, O.D.) of monochromatic (405 nm or 540 nm) light passing through a cuvette as an enzymatic or immunological reaction takes place.

The principle underlying the measurement of absorbance is depicted in the Schema 2 below:

Schema 2: Measurement principle of absorbance



Incident light (l_0) entering the cuvette is partially absorbed by the reaction medium as it passes through.
The transmitted light ($I_1 = I + I_p$) is measured.
The effect of stray light (I_p) is eliminated by taking two measurements of transmitted light within a brief interval:
$I_1 = I + I_p$ (first measurement which includes incident light and stray light)
$I_2 = I_p$ (second measurement, while blocking incident light, corresponds to the stray light)
l_2 is subtracted from l_1 to obtain I, which corresponds to light resulting only from incident light. Stray light (I_p) is assumed to remain constant between the two measurements.

The absorbance is calculated using the following equation:

$$A = -\log(I/I_0)$$ note: log decimal

Monochromatic incident light (I_0) is produced by passing light from a tungsten-halogen lamp through a 405 nm or 540 nm monochromatic filter, placed in a mobile filter holder.

These parts are located inside the optical module. The monochromatic light is directed from the optical module to the measurement heads by optical fibers, then another set of optical fibers carries the light from the measurement heads to the photometry measurement board.

G. Substantial Equivalence

The STA R Max® and its Predicate Device, STA-R Evolution® Expert Series (K093001) have the same Indications for Use, Technology, Principles of Operation and comparable Performances as described in Table 1.

Table1. Substantial Equivalence Comparison

Characteristics or Attributes	Diagnostica Stago, STA R Max®	Diagnostica Stago, STA-R Evolution® Expert Series	Identical/ Different
510(k) number	**510(k) subject device**	**K093001**	**N/A**
Indications for Use/Intended Use	The STA R Max® is a fully automatic clinical instrument indicated and intended for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.	The STA-R Evolution® Expert Series is a fully automatic clinical instrument indicated and intended for the performance of tests on human plasmas, the results of which aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy.	Identical
Target Population	To aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy in patients.	To aid in the diagnosis of coagulation abnormalities or in monitoring anticoagulant therapy in patients.	Identical
Anatomical Sites	In vitro testing of human plasma	In vitro testing of human plasma	Identical
Point of use	Hospital Laboratory or other Health Care Laboratory.	Hospital Laboratory or other Health Care Laboratory.	Identical
Chronometric Method of Coagulation Detection	Mechanical measurement of the oscillation of the metal ball in the cuvette.	Mechanical measurement of the oscillation of the metal ball in the cuvette.	Identical
Photometric method of Coagulation Detection	Light absorption technique provided by a filtered light source (405µm, 540µm).	Light absorption technique provided by a filtered light source (405µm, 540µm).	Identical

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Characteristics or Attributes		Diagnostica Stago, STA R Max®	Diagnostica Stago, STA-R Evolution® Expert Series	Identical/ Different
Electrical Safety		UL Listed. + IEC 61010-2-101:2003 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.	UL Listed. + IEC 61010-2-101:2003 – Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.	Identical
Dimensions	Height	1265 mm	1250 mm	Different
	Width	1220 mm	1280 mm	Different
	Depth	805 mm	820 mm	Different
Integrated PC	µprocessor	Intel Celeron M423 1.06 GHz	Pentium MMX (200MHz Min)	Different
	Memory	1 GB	64Mb (Min)	Different
	Hard disk	80 GB	2.4 GB (Min)	Different
Weight		238 kg	226 kg	Different
Barcode ID of samples and reagents		Yes	Yes	Identical
Connections		RS232, USB, RJ45	RS232	Different
Disk		None (external USB CD/DVD optional)	CD/DVD recorder, floppy disk	Different
Computer table		Yes (with 6 x 2.0 USB ports to connect the following USB peripheral devices: keyboard, mouse, touchscreen, printer, USB flash drive)	Yes (unconnected)	Different
Touch Screen		Yes	Yes (optional)	Different
Disposables		identical	identical	Identical

Comparison between the predicate and subject devices have minor differences. The differences are a result of the obsolescence of computer peripherals such as floppy discs, computer processors, and the addition of the new graphic interface and evolution of the communication protocol have no impact on performance, principle of operation, or

fundamental technology. The modifications of external design (e.g. color, weight, dimension, and shape) are ergonomic and cosmetic enhancements, which neither affect the fundamental technology, nor raise any new questions of safety and effectiveness. Thus the two devices are substantially equivalent with respect to their key attributes.

Conclusion

The STA R Max® and its Predicate Device, STA-R Evolution® Expert Series (K093001), have the same Intended Use/Indications for Use, same fundamental technology, same principles of operation, and comparable performance characteristics. The modifications consist of changes to the software (to integrate a new graphical user interface and a new communication protocol), new peripherals, and new external shape (for ergonomic improvements).

As evidenced by risk assessment and verification and validation activities, no new questions of safety and effectiveness were raised. Therefore we believe, the STA R Max® is substantially equivalent to the STA-R Evolution® Expert Series (K093001) predicate device.