Attachment_10

K130090

510(k) Summary

STA Compact Max®

FEB 1 2 2013

A. 510(k) Submitter information

Submitter's name	Diagnostica STAGO Inc.
Address	5 Century Drive Parsippany, New Jersey 07054
Phone Number	973.631.1200
Fax Number	973.867.6030
Date of Preparation	01/11/2013

Application Correspondent and Contact Person information

Name	Carlo d'Alessandro Director, IVD Quality and Regulatory Donawa Lifescience Consulting
Address	Piazza Albania, 10 - 00153 Rome, Italy
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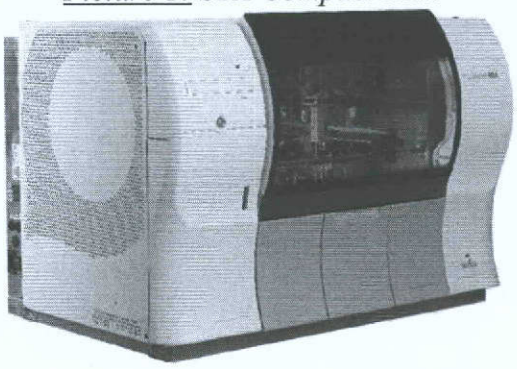
Fax Number	+39 06 574 3786

B. Device Information

Device Trade Name	STA Compact 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

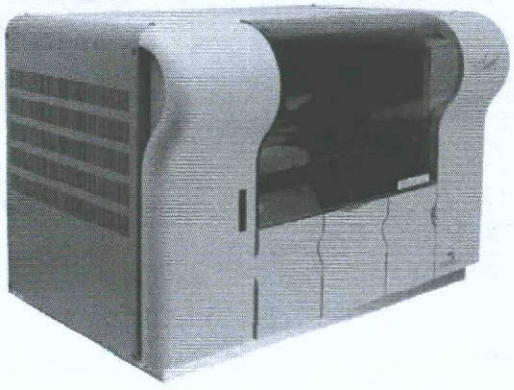
Picture 1: STA Compact Max®



C. Predicate Device Information

510(k) Number	K093167
Device Trade Name	STA Compact®.Automated Multi-Parametric Analyzer
Device Common Name	STA Compact® 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 Compact® (K093167)



D. Indication/Intended Use

The STA Compact Max® is a fully automatic clinical analyzer 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 Compact Max® is a modification to the company's own legally marketed device, STA Compact® (K093167).

The modifications of the device involve:

-1- Change of the on-board computer to allow the use of current technologies for data transfer (USB, DVD), without any change in the technology or mechanical operation by which samples are processed.

-2- Change of the operating system: from DOS for the predicate device to Windows for the STA Compact Max®.

-3- Migration of the user/application software to accommodate the new operating system, the use of new peripherals (USB, DVD, touch screen) and update the graphical user interface without modification of specifications and functionalities.

-4- Change of the external design (colors and shape) of the analyzer to refresh external aspect.

F. Description of the device

Diagnostica Stago's STA Compact Max® is a fully automatic clinical laboratory designed as a modification to the company's previously cleared STA Compact® analyzer (K093167). 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

STA Compact Max® is a fully automatic clinical laboratory analyzer. 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, support for instrument maintenance, and work load 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 permits reagent management simple. Manual entry of reagent information enables the use of non-barcoded reagents. The instrument performs multiple test methodologies in random access as selected by the user. These include clotting time or clot-based tests (i.e. chronometric) measurements and photometric assays (at specific wave lengths) on plasma samples.

2) Fundamental technologies

The proposed device has same fundamental technological characteristics as the predicate device based on the following:

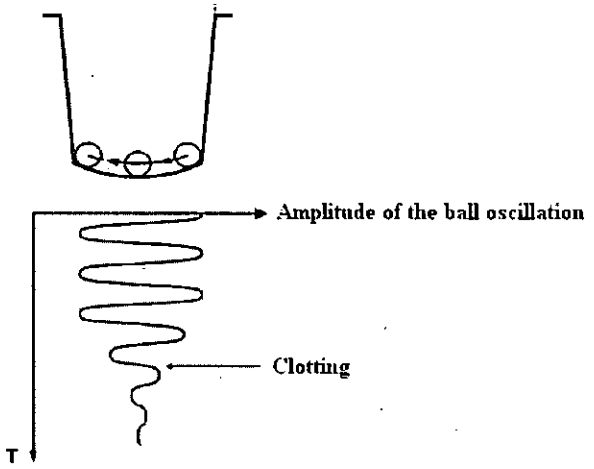
- Chronometry Measurement Principle

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

- thanks to the two curved rail tracks of the cuvettes
- and an alternate electro-magnetic field created by two independent coils.

The oscillation amplitude is constant when the environment has a constant viscosity. The oscillation amplitude decreases when the environment viscosity increases as shown in Schema 1.

Schema 1: Amplitude of the ball oscillation during clotting

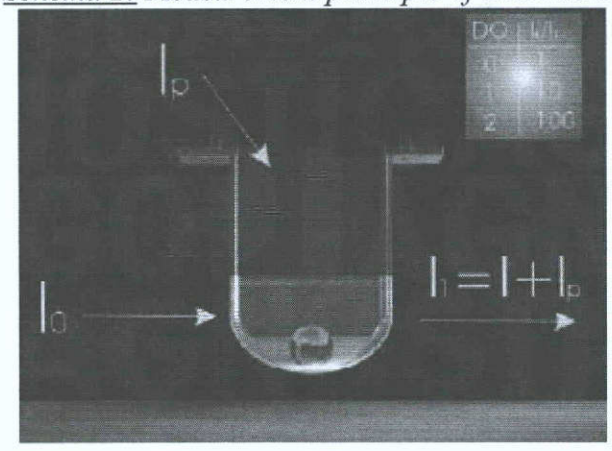


- Photometry Measurement Principle

The detection of chromogenic assays is based on the absorbance (optical density: O.D) of monochromatic light passing through the cuvette as a chromogenic reaction takes place.

Incident light entering the cuvette is partially absorbed by the reaction mixture as it passes through. The transmitted light is measured, and converted to absorbance. The Beer-lambert law is applied to convert absorbance to concentration of the substance being measured. The principle of absorbance measurement is depicted by the Schema 2.

Schema 2: Measurement principle of absorbance



G. Substantial Equivalence

The STA Compact Max® and its Predicate Device, STA Compact® (K093167) have the same Indications for Use, Technology, Principles of Operation and comparable Performances as described in Table 1.

Table 1: Substantial Equivalence Comparison

Characteristics or Attributes	Diagnostica Stago, STA Compact Max®	Diagnostica Stago, STA Compact®
510(k) number	**510(k) subject device**	**K093167**
Indications for Use/Intended Use	The STA Compact 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 Compact® 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.
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.

Anatomical Sites	In vitro testing of human plasma	In vitro testing of human plasma
Point of use	Hospital Laboratory or other Health Care Laboratory.	Hospital Laboratory or other Health Care Laboratory.
Fundamental Scientific Technology	There is no change in the Fundamental Scientific technology used. No new question generated.	No new questions demonstrated in K093167.
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.
Photometric method of Coagulation Detection	Light absorption technique provided by a filtered light source.	Light absorption technique provided by a filtered light source.
Design Control	Design Controls: Verification and Validation utilized.	Design Controls: Verification and Validation utilized.
Electrical Safety	UL Listed.	UL Listed.
Performance	Same as Predicate Device	See K093167

The specific differences between the instruments are the on-board computer, to allow the use of Windows operating system, new peripherals (USB, CD/DVD), and the migration of the application software with a new graphical user interface. The purposes are to improve the ease of use, to include operator/user use enhancements and to manage obsolescence (See Table 2). These modifications don't change, delete or add functionalities.
The modifications of external design: color and shape, are only a marketing purpose, and has no impact on performances, principles of operation or fundamental technologies.

Table 2: Minor Modifications comparison

Features		**STA Compact Max®**	**STA Compact®** Predicate Device K093167
Dimensions	Height	705 mm (27.75 in)	640mm (26.5 in)
	Width	970 mm (38.18 in)	975mm (38.4 in)
	Depth	730 mm (28.73 in) lower part 685 mm (26.97in)	720mm (28.3 in) lower part 657 mm (25.9 in)
Weight		140 kg (331 lbm)	140 kg (331 lbm)
Barcode ID of samples and reagents		Yes	Yes
Integrated PC		Yes	Yes
Connections		USB, RJ45, Port parallel	Port parallel
Disk		CD/DVD disk	floppy disk
Touch Screen		Yes	No
Optical Wavelengths		405µm, 540µm	405µm, 540µm
Mechanical clotting		Yes	Yes
Disposables		identical	identical

Firmware versions of STA Compact Max® and its predicate device, STA Compact® are strictly identical as described below.

Table 3: Firmware versions shared by STA Compact Max® and STA Compact®

Name	Version	Description
MSTB	V1.00	Measurement
GSTB	V4.72	Management of the measurement and its environment
ISTB	V3.10	Identification of the products and sample (controlling barre code reader)
CSTB	V10.42	Needles control (z axis).
	V1.81	Needles control (z axis) with cap piercing
MPP	V2.81	Arms and pipetting control

Conclusion

The STA Compact Max® and its Predicate Device, STA Compact® (K093167), have the same Intended Use/Indications for Use, same fundamental technological characteristics, principles of operation and comparable performances characteristics. The modifications consist in a new PC on-board computer, with new operating system, new peripherals, a new graphical user interface to include operator/user use enhancements and to improve easy to use.

As evidenced by Risk Assessment and Validation Studies, no new questions were raised regarding the Safety, Effectiveness, Performance, Indication for Use, Technology and the Principles of Operation. Therefore, The STA Compact Max® is substantially equivalent to the STA Compact® Predicate Device.

Attachment_05

Proposed Labeling

Symbol	Meaning
	Alternating current
	Direct Current
	Protective conductor terminal
	Off (Power)
	On (Power)
	Caution, risk of electric shock
	Caution, hot surface
	Caution, consult the provided documentation for important cautionary information such as warnings and precautions
	Caution, biological risks
IVD	In vitro diagnostic medical device
	Medical device manufacturer
	Separate collection: do not discard with other waste. For additional information about the disposal procedure, *see chapter 1.8.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

Diagnostica Stago, Inc.
c/o Mr. Carlo d'Alessandro,
Director, IVD Quality and Regulatory
Donawa Lifescience Consulting
Piazza Albania, 10
Rome, Italy 00153

February 12, 2013

Re: k130090
Trade/Device Name: STA Compact Max®
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: JPA
Dated: January 11, 2013
Received: January 18, 2013

Dear Mr. d'Alessandro:

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 Part 801); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Attachment_01

Indications for Use

510(k) Number (if known): K130090

Device Name: STA Compact Max®

Indications for Use:

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

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety
510(k) K130090