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K093167

Attachment – 6

DEC 22 2009

510 (k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Umberto V. Parrotta, Jr.
Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

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Contact Person: Umberto V. Parrotta, Jr.

Date Prepared: October 05, 2009.

Name of Modified Device and Name/Address of Sponsor:

STA Compact® Automated Multi-Parametric Analyzer or STA Compact®.

Diagnostica Stago, Inc.
Five Century Drive
Parsippany, New Jersey 07054

Common or Usual Name:

- IVD Coagulation Device/Instrument.
- Automated and Semi-Automated Hematology Device.
- Multi-Parametric Analyzer

Classification Name:

System, Multipurpose for In Vitro Coagulation Studies

Predicate Device:

Diagnostica Stago's STA Compact® Automated Multi-Parametric Analyzer (K961579).

Purpose of the Special 510(k) Notice:

The STA Compact® is a modification to the company's own legally marketed device, STA Compact® (K961579).

The modification of the device involves replacement of components for reliability of operation or obsolescence reasons, change in the device application software to provide operator/user use enhancements and modification of the data post-processing to increase results reliability. The software modification essentially consists of

addition of a quality improvement function which provides *Hook Effect Detection* when the vWF (Von Willebrand factor) test is performed on the sample plasma.

Indication/Intended Use:

The STA Compact® Automated Multi-Parametric Analyzer 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.

Principles of Operation:

The STA Compact® Automated Multi-Parametric Analyzer 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, 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 wavelengths) on plasma samples.

The STA Compact® is the modified version of the Company's STA Compact® (K961579), legally marketed Predicate Device. The modification of the device involves replacement of components for reliability of operation or obsolescence reasons, change in the device application software to provide operator/user use enhancements and modification of the data post-processing to increase results reliability.

Principles of Operation for the aforementioned analyses are the same between the subject submission device and the Predicate Device.

Substantial Equivalence:

The STA Compact® and its Predicate Device, STA Compact® (K961579) have the same Indications for Use, Technology, Principles of Operation and comparable Performances. The previously mentioned characteristics have been slightly modified to improve performance, without changing the principle of operation or the technological characteristics. The modifications consist of new hardware and mechanical components to increase the operation reliability or to replace obsolete components. The software is also updated to include operator/user use enhancements and modification of the data post-processing is done to increase results reliability. The software modification, subject of this Special 510(k) essentially consists of addition of a function, *Hook Effect Detection* when the vWF test is performed on the sample

plasma. This function is operational during vWF (Von Willebrand factor) testing. This function identifies the hook effect (showing abnormally low results for high concentrations of the vWF factor) which subsequently allows the instrument to perform appropriate re-dilutions to obtain reliable results.

As evidenced by Risk Assessment and Validation Studies (including all the changes mentioned above), no new questions were raised regarding the Safety, Effectiveness, Performance, Indications for Use, Technology and the Principles of Operation. Therefore, the STA Compact® is Substantially Equivalent to the STA Compact® Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

DEC 22 2009

Diagnostica Stago, Inc.
c/o Umberto V. Parrotta
Director of Regulatory Affairs and Quality Assurance
5 Century Drive
Parsippany, New Jersey 07054

Re: K093167
Trade/Device Name: STA Compact® Automated Multi-Parametric Analyzer
Regulation Number: 21 CFR 864.7290
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: December 4, 2009
Received: December 8, 2009

Dear Mr. Parrotta:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

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

Enclosure

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Attachment - 2A

Indications for Use

510(k) Number (if known): K093167

Device Name: STA Compact® Automated Multi-Parametric Analyzer

Indications for Use:

The STA Compact® Automated Multi-Parametric Analyzer 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.

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) K093167