K093170

CONFIDENTIAL

Stago

DEC 22 2009

Attachment – 5

510(k) SUMMARY

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

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

Phone: (973) 631-1200, x-2044
Facsimile: (973) 695-0095

Contact Person: Umberto V. Parrotta

Date Prepared: July 17, 2009

Name of Device and Name/Address of Sponsor:

STA® - Liatest® Free PS

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

Common or Usual Name:

- Free Protein S IVD Device.
- IVD Factor Deficiency Test.

Classification Name:

- Factor Deficiency Test.

Predicate Device:

- STA® - Liatest® Free Protein S (K010963).

Purpose of the Special 510(k) Notice:

- STA® - Liatest® Free PS is a modification of the Company's previously FDA cleared device, STA® - Liatest® Free Protein S. Specifically, the currently marketed product (predicate device) is pre-calibrated, whereas the calibration for the modified device (the subject of this submission) is performed with a set of calibrator plasmas (Diagnostica Stago's STA® - Free PS Calibrator)

510(k) SUMMARY

Indication/Intended Use:

The STA® - Liatest® Free PS kits are intended for use with analyzers of the STA® line suitable with these reagents for the antigenic assay of free Protein S in plasma by the immuno-turbidimetric method.

Technological Characteristics:

The STA® - Liatest® Free PS test kit is comprised of a suspension of latex microparticles coated with two (2) different mouse monoclonal anti-human free protein S antibodies stabilized with bovine albumin. Also in the test kit is an HEPES buffer. Testing is carried out in citrated human plasma via the immuno-turbidimetric method utilizing external calibrator plasmas for the STA® - Liatest® Free PS (the predicate device is pre-calibrated, not utilizing external calibrator plasmas).

Substantial Equivalence:

The STA® - Liatest® Free PS and the predicate device, STA® - Liatest® Free Protein S (K010963) are identical products regarding indication/intended use, formulation or materials of construction, technology, and safety. The primary difference between the subject product and predicate device is the use of an external calibrator for the subject product of this submission versus pre-calibration for the predicate device. This difference is accounted in the procedure section of the package insert. Based upon the aforementioned comparisons and those designated in the SE Comparison Chart, the product, STA® - Liatest® Free PS and the predicate device, STA® - Liatest® Free Protein S are similar in indication/intended use, technology, principles of operation, and application of use (with IVD medical devices) thus yielding no new questions in safety, effectiveness, or technology. Therefore, this concludes the product STA® - Liatest® Free PS is substantially equivalent to the predicate device, STA® - Liatest® Free Protein S (K010963).

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: K092170
Trade/Device Name: STA® Liatest® Free PS
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: November 25, 2009
Received: November 27, 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 – 1

Indications for Use

510(k) Number (if known): K092170

Device Name: STA®- Liatest® Free PS.

Indication for Use:

The STA® - Liatest® Free PS kits are intended for use with analyzers of the STA® line suitable with these reagents for the antigenic assay of free Protein S in plasma by the immuno-turbidimetric method.

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) K092170