Stago

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Attachment – 4

510(k) Summary

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

K092937

Umberto V. Parrotta, Jr.
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Parsippany, New Jersey 07054

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AUG 0 2 2010

Contact Person: Umberto V. Parrotta, Jr.

Date Prepared: September 23, 2009

Name of Device and Name/Address of Sponsor:

STA® - Hybrid Hep Calibrator

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

Common or Usual Name:

- IVD Coagulation Calibration Device.
- IVD Calibrator.

Classification Name:

- Name: Calibrator, Secondary.
- Description: Calibrator

Predicate Device:

- STA® - Calibrator HBPM/LMWH Kit (K010350).
- STA® - Hepanorm® H (K854762) {formerly cleared as Hepanorm® Calibration Plasma Set}.

Purpose of the Traditional 510(k) Notice:

STA® - Hybrid Hep Calibrator is a new device that bundles two of the Company's previously FDA cleared devices, STA® - Hepanorm® H and STA®- Calibrator

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HBPM/LMWH into a single kit. Thus, the primary difference between the subject product and predicate devices is that it contains a set of calibration plasmas for calibration of assays of unfractionated heparin (UFH) and Low Molecular Weight Heparin (LMWH) bundled together in a single kit.

Indication/Intended Use:

The STA® - Hybrid Hep Calibrator is a set of calibrator plasmas intended for use with analyzers of the STA® line suitable to these reagents, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-Xa activity using the chromogenic method, STA® - Rotachrom® Heparin.

Technological Characteristics:

- The STA® - Hybrid Hep Calibrator is a set of lyophilized human plasmas used to create the calibration curve on the STA® line of IVD instruments performing the chromogenic method for heparin (UFH and LMWH) assays.
- Each STA® - Hybrid Hep Calibrator available contains:
  - 4 x 1-ml vials of Reagent 1: STA® - Hybrid Hep Calibrator ⓪, lyophilized human plasma free of heparin.
  - 4 x 1-ml vials of Reagent 2: STA® - Hybrid Hep Calibrator ③, lyophilized human plasma containing a well-defined quantity of UFH.
  - 4 x 1-ml vials of Reagent 3: STA® - Hybrid Hep Calibrator ⑥, lyophilized human plasma containing a well-defined quantity of UFH that is greater than that of Reagent 2.
  - 4 x 1-ml vials of Reagent 4: STA® - Hybrid Hep Calibrator ⑨, lyophilized human plasma containing a well-defined quantity of LMWH.
  - 4 x 1-ml vials of Reagent 5: STA® - Hybrid Hep Calibrator ⑱, lyophilized human plasma containing a well-defined quantity of LMWH that is greater than that of Reagent 4.

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Principles of Operation

The STA® - Hybrid Hep Calibrator is designed to operate utilizing the STA® product line of IVD coagulation analyzers for the purpose of creating calibration curves for assays of heparin by measuring the anti-Xa activity. While the subject device performs calibration of assays based on chromogenic method, the predicate devices perform calibration of assays based on chromogenic method and on clotting method, both being anti-Xa method.

Substantial Equivalence:

The STA® - Hybrid Hep Calibrator, the subject product of this submission, and the predicate devices, STA® - Calibrator HBPM/LMWH Kit and STA® - Hepanorm® H are identical products regarding indication/intended use, formulation or materials of construction and design, technology, and safety. The primary difference between the subject product and predicate devices is that the product contains a set of calibration plasmas for assays of both unfractionated heparin (UFH) and Low Molecular Weight Heparin (LMWH) bundled in a single kit whereas the predicate devices are marketed as two (2) separate and distinct products – one kit for UFH and the other kit for LMWH. In summary, the predicate devices are bundled together as a single kit. The STA® - Hybrid Hep Calibrator like the predicate devices, is a calibrator used in creating the calibration curve on IVD devices for the purpose of Heparin activity assay by measuring the anti-Xa activity.

The product, STA® - Hybrid Hep Calibrator and the predicate devices, STA® - Hepanorm® H and STA®- Calibrator HBPM/LMWH 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® - Hybrid Hep Calibrator is substantially equivalent to the predicate devices, STA® - Calibrator HBPM/LMWH Kit (K010350) and STA® - Hepanorm® H {previously cleared as Hepanorm® Calibration Plasma Set} (K854762).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

AUG 0 2 2010

Re: k092937
Trade/Device Name: STA® - Hybrid Hep Calibrator
Regulation Number: 21 CFR 864.7525
Regulation Name: Heparin Assay
Regulatory Class: Class II
Product Code: KFF, JIT
Dated: July 21, 2010
Received: July 22, 2010

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

AUG 0 2 2010

510(k) Number (if known): K092937

Device Name: STA®- Hybrid Hep Calibrator.

Indication for Use:

The STA® - Hybrid Hep Calibrator is a set of calibrator plasmas intended for use with analyzers of the STA® line suitable to these reagents, for the calibration of heparin (UFH and LMWH) activity assay by measuring the anti-Xa activity using the chromogenic method, STA® - Rotachrom® Heparin.

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) K092937