510(k) Summary

MAY 21 2010

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
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Preparation Date:	March 3, 2010

Device Trade Names:

HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG
HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM
HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG Controls
HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM Controls

Regulatory Information:

Classification Name:	Multiple autoantibodies immunological test system; Single (specified) analyte controls (assayed and unassayed)
Device Class:	Class II (Assays); Class I (Controls)
Regulation No.:	21 CFR 866.5660 (Assays); 21 CFR 862.1660 (Controls)
Product Code:	MSV (Antibodies, β_2 Glycoprotein I); JJX (Controls)
Panel:	Immunology

Identification of Predicate Devices:

K031208	REAADS IgG anti-β_2 GPI Test Kit
K031208	REAADS IgM anti-β_2 GPI Test Kit

Device Indications for Uses:

- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgG antibodies in human citrated plasma and serum on the ACL AcuStar, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.
- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgM antibodies in human citrated plasma and serum on the ACL AcuStar as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.
- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG Controls:** For the quality control of the Anti-β_2 Glycoprotein-I IgG assay performed on the ACL AcuStar.
- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM Controls:** For the quality control of the Anti-β_2 Glycoprotein-I IgM assay performed on the ACL AcuStar.

Device Description:

- **HemosIL AcuStar Anti-β2 Glycoprotein-I IgG** is a chemiluminescent two-step immunoassay consisting of magnetic particles coated with human purified β_2GPI which capture, if present, the anti-β_2GPI antiphospholipid antibodies from the sample. After incubation, magnetic separation, and a wash step, a tracer consisting of an isoluminol-labeled anti-human IgG antibody is added and may bind with the captured anti-β_2GPI IgG on the particles. After a second incubation, magnetic separation, and wash step, reagents that trigger the luminescent reaction are added, and the emitted light is measured as relative light units (RLUs) by the ACL AcuStar optical system. The RLUs are directly proportional to the anti-β_2GPI IgG concentration in the sample.

  The ACL AcuStar anti-β_2GPI IgG assay utilizes a 4 Parameter Logistic Curve (4PLC) fit data reduction method to generate a Master Curve. The Master Curve is predefined and lot dependent and it is stored in the instrument through the cartridge barcode. With the measurement of calibrators, the predefined Master Curve is transformed to a new, instrument specific 4PLC Working Curve. The concentration values of the calibrators are included in the calibrator tube barcodes.

- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM** is a chemiluminescent two-step immunoassay consisting of magnetic particles coated with human purified β_2GPI which capture, if present, the anti-β_2GPI antiphospholipid antibodies from the sample. After incubation, magnetic separation, and a wash step, a tracer consisting of an isoluminol-labeled anti-human IgM antibody is added and may bind with the captured anti-β_2GPI IgM on the particles. After a second incubation, magnetic separation, and wash step, reagents that trigger the luminescent reaction are added, and the emitted light is measured as relative light units (RLUs) by the ACL AcuStar optical system. The RLUs are directly proportional to the anti-β_2GPI IgM concentration in the sample.

  The ACL AcuStar anti-β_2GPI IgM assay utilizes a 4 Parameter Logistic Curve (4PLC) fit data reduction method to generate a Master Curve. The Master Curve is predefined and lot dependent and it is stored in the instrument through the cartridge barcode. With the measurement of calibrators, the predefined Master Curve is transformed to a new, instrument specific 4PLC Working Curve. The concentration values of the calibrators are included in the calibrator tube barcodes.

- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG Controls:** The Low and High Anti-β_2 Glycoprotein-I IgG Controls are prepared by means of a dedicated process and contain different concentrations of human anti-β_2 Glycoprotein-I IgG antibodies.
  - **Low Anti-β_2 Glycoprotein-I IgG Control:** Control intended for the assessment of precision and accuracy of the assay at the normal or around cut-off anti-β_2 Glycoprotein-I IgG levels.
  - **High Anti-β_2 Glycoprotein-I IgG Control:** Control intended for the assessment of precision and accuracy of the assay at the abnormal anti-β_2 Glycoprotein-I IgG levels.

- **HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM Controls:** The Low and High Anti-β_2 Glycoprotein-I IgM Controls are prepared by means of a dedicated process and contain different concentrations of human anti-β_2 Glycoprotein-I IgM antibodies.
  - **Low Anti-β_2 Glycoprotein-I IgM Control:** Control intended for the assessment of precision and accuracy of the assay at the normal or around cut-off anti-β_2 Glycoprotein-I IgM levels.
  - **High Anti-β_2 Glycoprotein-I IgM Control:** Control intended for the assessment of precision and accuracy of the assay at the abnormal anti-β_2 Glycoprotein-I IgM levels.

Technological Characteristic Summary:

The HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG assay used with HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG Controls are equivalent to the currently marketed REAADS IgG Anti-β_2GPI Test Kit (K031208). The HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM assay used with HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM Controls are equivalent to the currently marketed REAADS IgM Anti-β_2 GPI Test Kit (K031208).

Substantial Equivalence Comparison Table:

Characteristic	New Device: HemosIL AcuStar Anti-β_2 GPI IgG	Predicate Device: REAADS IgG Anti-β_2GPI (K031208)	New Device: HemosIL AcuStar Anti-β_2 GPI IgM	Predicate Device: REAADS IgM Anti-β_2GPI (K031208)
Intended Use	Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgG antibodies in human citrated plasma and serum on the ACL AcuStar, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.	For the detection and semi-quantitation of IgG anti-β_2 GPI antibodies in human serum or plasma as an aid for assessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).	Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgM antibodies in human citrated plasma and serum on the ACL AcuStar as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.	For the detection and semi-quantitation of IgM anti-β_2GPI antibodies in human serum or plasma as an aid for assessing the risk of thrombosis in individuals with systemic lupus erythematosus (SLE) and lupus-like disorders (anti-phospholipid syndrome).
Technology	Two-step chemiluminescent immunoassay	ELISA	Two-step chemiluminescent immunoassay	ELISA
Assay format	Semi-quantitative	Same	Semi-quantitative	Same
Sample type	Serum or Citrated Plasma	Same	Serum or Citrated Plasma	Same
Calibrator	Two Calibrator Levels (Included in test kit)	Three Calibrator Levels (Included in Test Kit)	Two Calibrator Levels (Included in test kit)	Three Calibrator Levels (Included in Test Kit)
Quality Control	Low and High Controls (Sold Separately)	Normal and Positive Controls (Included in Test Kit)	Low and High Controls (Sold Separately)	Normal and Positive Controls (Included in Test Kit)
Clinical Cut-off	20.0 U/mL	20 G Units	20.0 U/mL	20 M Units

Summary of Performance Data:

Precision

Within run and total precision assessed over multiple runs using the respective assays with their two control levels and a plasma sample giving the following results:

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG

ACL AcuStar	Mean (U/mL)	CV% (Within run)	CV% (Total)
Low anti-β_2GPI IgG Control	19.1	7.8%	11.2%
High anti-β_2GPI IgG Control	429	3.0%	3.8%
Anti-β_2GPI IgG plasma sample A	14.7	6.9%	10.9%
Anti-β_2GPI IgG plasma sample B	20.9	4.7%	7.3%
Anti-β_2GPI IgG plasma sample C	58.1	3.2%	5.0%
Anti-β_2GPI IgG plasma sample D	508	2.5%	3.3%
Anti-β_2GPI IgG plasma sample E	1470	2.5%	3.7%
Anti-β_2GPI IgG plasma sample F	2694	3.7%	3.7%

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM

ACL AcuStar	Mean (U/mL)	CV% (Within run)	CV% (Total)
Low anti-β_2GPI IgM Control	4.32	3.4%	6.4%
High anti-β_2GPI IgM Control	63.0	2.4%	4.3%
Anti-β_2GPI IgM plasma sample A	11.0	3.6%	5.8%
Anti-β_2GPI IgM plasma sample B	13.6	4.5%	8.3%
Anti-β_2GPI IgM plasma sample C	16.3	2.7%	6.6%
Anti-β_2GPI IgM plasma sample D	91.9	2.4%	5.7%
Anti-β_2GPI IgM plasma sample E	302	3.0%	5.2%
Anti-β_2GPI IgM plasma sample F	510	4.1%	6.0%

Summary of Performance Data (Cont.):

Outcome Studies

Outcome studies were performed on 321 selected frozen citrated plasmas. These plasmas were from 6 different groups including selected individuals diagnosed as primary APS (PAPS), secondary APS (SAPS) systemic lupus erythematosus (SLE) but not APS and SLE-like by standard objective tests. The fifth group was patients with cardiovascular disorders but not classified in the previous four groups. A group of apparently healthy people was also included.

The results summarized below are based on a cut-off of 20 U/mL:

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG

Patient group	N	N (Positive)	% Positive
PAPS	23	14	60.9%
SAPS	69	45	65.2%
SLE	115	20	17.4%
SLE-like	5	0	0.0%
Others	6	1	16.7%
Normals	103	0	0.0%

Considering as positive the patient groups PAPS and SAPS the clinical Sensitivity, Specificity and Overall % Agreement were:

System	N	Sensitivity (95% CI)	Specificity (95% CI)	% Agreement (95% CI)
ACL AcuStar	321	64.1% (53.5%-73.9%)	90.8% (86.3%-94.2%)	83.2% (78.6%-87.1%)

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM

Patient group	N	N (Positive)	% Positive
PAPS	23	7	30.4%
SAPS	69	20	29.0%
SLE	115	10	8.7%
SLE-like	5	0	0.0%
Others	6	1	16.7%
Normals	103	0	0.0%

Considering as positive the patient groups PAPS and SAPS, the clinical Sensitivity, Specificity and Overall % Agreement were:

System	N	Sensitivity (95% CI)	Specificity (95% CI)	Agreement (95% CI)
ACL AcuStar	321	29.3% (20.3%-39.8%)	95.2% (91.6%-97.6%)	76.3% (71.3%-80.9%)

Summary of Performance Data (Cont.):

Method Comparison Studies

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgG

The samples used in the clinical performance study that were within the compared methods' test ranges were measured in a Method Comparison study with REAADS IgG Anti-β_2GPI Test Kit. % Positive, Negative and Overall Agreement were:

	ELISA Assay	
HemosIL AcuStar Anti-β_2GPI IgG	Negative	Positive
Negative	80	0
Positive	19	51

Predicate Device	N	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Overall Agreement (95% CI)
ELISA Assay	150	100.0% (93.0%-100.0%)	80.8% (71.7%-88.0%)	87.3% (80.9%-92.2%)

HemosIL AcuStar Anti-β_2 Glycoprotein-I IgM

The samples used in the clinical performance study that were within the compared methods' test ranges were measured in a Method Comparison study with REAADS IgM Anti-β_2GPI Test Kit. % Positive, Negative and Overall Agreement were:

	ELISA Assay	
HemosIL AcuStar Anti-β_2GPI IgM	Negative	Positive
Negative	153	17
Positive	5	30

Predicate Device	N	% Positive Agreement (95% CI)	% Negative Agreement (95% CI)	% Overall Agreement (95% CI)
ELISA Assay	205	63.8% (48.5%-77.3%)	96.8% (92.8%-99.0%)	89.3% (84.2%-93.2%)

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Instrumentation Laboratory Co.
c/o Carol Marble
Regulatory Affairs Director
113 Hartwell Avenue
Lexington, MA 02421

MAY 2 1 2010

Re: k091556

Trade/Device Name:	HemosIL™ AcuStar Anti-β2 Glycoprotein-I IgG HemosIL™ AcuStar Anti-β2 Glycoprotein-I IgM HemosIL™ AcuStar Anti-β2 Glycoprotein-I IgG Controls HemosIL™ AcuStar Anti-β2 Glycoprotein-I IgM Controls
Regulation Number:	21 CFR §866.5660
Regulation Name:	Multiple autoantibodies immunological test system
Regulatory Class:	Class II
Product Code:	MSV, JJX
Dated:	May 14, 2010
Received:	May 17, 2010

Dear Carol Marble:

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

Indications for Use Statement

510(k) Number (if known): K091556

Devices Name: HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG
HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG Controls

Indications for Use:

- **HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgG antibodies in human citrated plasma and serum on the ACL AcuStar™, as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.

- **HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgG Controls:** For the quality control of the Anti-β_2 Glycoprotein-I IgG assay performed on the ACL AcuStar.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k091556

Indications for Use Statement

510(k) Number (if known): K091556

Devices Name: HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM
HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM Controls

Indications for Use:

- **HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM:** Fully automated chemiluminescent immunoassay for the semi-quantitative measurement of anti-β_2 Glycoprotein-I (anti-β_2GPI) IgM antibodies in human citrated plasma and serum on the ACL AcuStar™ as an aid in the diagnosis of thrombotic disorders related to primary and secondary Antiphospholipid Syndrome (APS) when used in conjunction with other laboratory and clinical findings.

- **HemosIL™ AcuStar Anti-β_2 Glycoprotein-I IgM Controls:** For the quality control of the Anti-β_2 Glycoprotein-I IgM assay performed on the ACL AcuStar.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Reena Philip
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Device Evaluation and Safety

510K k091556