Werfen Group | Instrumentation Laboratory

MAR 17 2011

510(k) Summary

(per 21 CFR 807.92)

I. Applicant Contact Information

Applicant:	Instrumentation Laboratory Co.
Address:	180 Hartwell Road Bedford, MA 01730
Contact Person:	Jacqueline Emery, BS EE
Phone Number:	781-861-4350
Fax Number:	781-861-4207
Email:	jemery@ilww.com
Preparation Date:	July 28, 2010
Device Trade Name	HemosIL® Protein S Activity

II. Device Regulatory Information

Regulatory Section	21 CFR 864.7290
Classification	Class II
Common Name:	Protein S Test
Classification Name:	Factor Deficiency Test
Product Code:	GGP
Panel:	81 (hematology)

III. Identification of Legally Marketed Device

K053499	HemosIL® ProS

IV. Device Description

The HemosIL Protein S Activity assay determines the functional activity of free Protein S by measuring the degree of prolongation of prothrombin time in the presence of the human recombinant factor, phospholipids, calcium ions, and activated Protein C. The protein S activity is correlated with the prolongation of the clotting time of a Protein S deficient plasma to which a diluted sample has been added.

V. Device Indications/ Intended Use

Automated coagulation functional assay for the quantitative determination of free Protein S in human citrated plasma as an aid in the diagnosis of hereditary and acquired Protein S deficiency, on ACL TOP Family members.

VI. Comparison of Technological Characteristics of the Device

Similarities

The HemosIL Protein S Activity Assay is Substantially Equivalent to its predicate, the HemosIL ProS Assay (K053499), in both intended use and performance:

TABLE 1: TABLE OF SIMILARITY AND DIFFERENCES

Item	Predicate Device	New Device
K#	K053499	TBD
Device Name	HemosIL ProS	HemosIL Protein S Activity
Manufacturer	Instrumentation Laboratory Co. (self)	Same
Indications for Use	Automated coagulation functional assay for the quantitative determination of free Protein S in human citrated plasma as an aid in the diagnosis of hereditary and acquired Protein S deficiency, on the ACL TOP® Family of analyzers.	Same
Sample Type	citrated plasma	Same
Test Principle	Functional Clotting Assay	Same
Methodology	The test is based on the ability of endogenous protein S as a cofactor of activated protein C to prolong the clotting time. Protein S levels in patient plasma are measured automatically on the ACL TOP® Family of analyzers. The test determines the functional activity of free protein S by measuring the degree of prolongation of a prothrombin time in the presence of the recombinant tissue factor, phospholipids, calcium ions, and activated protein C. The protein S activity is correlated with the prolongation of the clotting time of a Protein S deficient plasma to which diluted sample has been added.	Same
Calibration	HemosIL Calibration plasma values are assigned for Protein S Activity and used for calibrating the standard curve.	Same

TABLE 2: TABLE OF SIMILARITY AND DIFFERENCES (CONTINUED)

Item	Predicate Device	New Device
K#	K053499	TBD
Device Name	HemosIL ProS	HemosIL Protein S Activity
Kit Composition – Protein S reagent	– Lyophilized preparation containing recombinant tissue factor, synthetic phospholipids, activated protein C, Polybrene, buffer, stabilizers & preservatives. – *Includes* calcium ions. – *Rabbit* Tissue Factor	– Lyophilized preparation containing recombinant tissue factor, synthetic phospholipids, activated protein C, Polybrene, buffer, stabilizers & preservatives. – *Calcium* is *added separately* to improve shelf life. – *Human* Tissue Factor
– Calcium Reagent	– Calcium is included in the Protein S reagent vial.	– Calcium is included in a separate vial.
– Protein S deficient plasma	– Lyophilized human plasma which has been artificially depleted of protein S.	– Same except for vial size.
– Protein S control plasma	– Lyophilized human plasma containing a low level of protein S.	– Not sold with this product.

Differences

There are 2 main differences between the 2 products; the HemosIL Protein S Activity Assay, the subject of this submission, and its HemosIL ProS assay predicate: the applicant contains human tissue factor, whereas the predicate utilizes rabbit tissue factor.

In addition the HemosIL Protein S Activity assay kit composition has changed as compared to its predicate: the calcium ions required for the reaction, which were previously *included* in the predicate's Protein S reagent vial, are now offered as a *separate* component. The test results demonstrate that these changes do not adversely affect the product's performance.

VII. Summary of Performance Data

- *Precision*

Performance characteristics were assessed utilizing 3 lots of reagent on 3 representative members of the ACL TOP Family (ACL TOP, ACL TOP 500 CTS and ACL TOP 700). Precision was evaluated in accordance with CLSI EP05-A2[1], for 20 days, with 2 runs per day and 2 replicates per run, for each sample level (n=80/ instrument/ lot). Data from a representative lot is included below:

ACL TOP	Mean (% PS)	CV% (Within run)	CV% (Total)
Normal Control	94.2	2.5	4.9
Low Abnormal Control	33.6	3.8	7.1
High Abnormal Control	19.3	1.19(SD)	2.23 (SD)
Internal Control 1	44.5	2.9	6.2
Internal Control 2	67.2	1.7	4.7
High Plasma Sample	128	1.6	4.2

- *Method Comparison – In-House*

An in-house comparison study was performed in accordance with CLSI EP09-A2; Method Comparison and Bias Estimation, 2nd Edition, 2002, to compare the performance of HemosIL Protein S Activity versus the predicate device (HemosIL ProS) on representative ACL TOP Family members with the following results:

TABLE 3: METHOD COMPARISON RESULTS IN-HOUSE

System	n	Slope	R
ACL TOP	87	0.966	0.968
ACL TOP 500 CTS	45	1.046	0.975

[1] CLSI EP5-A2: *Evaluation of Precision Performance of Quantitative Measurement Methods*; Approved Guideline, 2nd edition.

- *Method Comparison – Field Sites*

  Two field site studies were performed to compare the performance of the HemosIL Protein S Activity assay versus the predicate device (HemosIL ProS) on the ACL TOP with the following results:

TABLE 4: METHOD COMPARISON RESULTS FIELD SITES

IL System	n	Slope	R
Site #1	129	0.984	0.965
Site #2	139	1.049	0.956

VIII. Conclusion

Based on the device's similarity in intended use, technology characteristics and performance data, it is determined that the IL HemosIL Protein S Activity assay is substantially equivalent to its predicate, the HemosIL ProS assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Instrumentation Laboratory Co.
c/o Ms. Jacqueline Emery
Regulatory Affairs Manager
180 Hartwell Rd.
Bedford, MA 01730

MAR 17 2011

Re: k102164
Trade/Device Name: HemosIL® Protein S Activity
Regulation Number: 21 CFR 864.7290
Regulation Name: Test Qualitative and Quantitative Factor Deficiency
Regulatory Class: Class II
Product Code: GGP
Dated: March 4, 2011
Received: March 7, 2011

Dear Ms. Emery,

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): K102164

Device Name: HemosIL® Protein S Activity

Indications for Use:

Automated coagulation functional assay for the quantitative determination of free Protein S in human citrated plasma as an aid in the diagnosis of hereditary and acquired Protein S deficiency, on the ACL TOP® Family of analyzers.

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

Division Sign-Off
Office of In Vitro Diagnostic ~~Device~~
Evaluation and Safety

510(k) K102164