K141116

JUL 25 2014

510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	LIASON® Anti-HAV, LIAISON® XL Analyzer
Common Names/Descriptions:	Hepatitis Anti-HAV, serological assay, Automated Chemiluminescent Immunoassay Analyzer
Regulation Number:	21 CFR 866.3310
Regulation Name:	Hepatitis A virus (HAV) serological assays
Regulation Class:	Class II
Product Codes:	LOL, JJF

PREDICATE DEVICES: LIAISON® XL Analyzer
Reference K103529

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® Anti-HAV assay is an in vitro chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

This assay is not intended for screening blood or solid or soft tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing assay performance characteristics in these populations. Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

The LIAISON XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for in vitro diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer. It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays.

The LIAISON® Control Anti-HAV (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Anti-HAV assay.

The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON®, LIAISON® XL and LIAISON® XL with LIAISON® XL Workcell Upgrade Kit.

DESCRIPTION:

The LIAISON® XL Analyzer is an *in vitro* diagnostic device consisting of loading areas (for samples, Reagent Integrals, ancillary reagents, Starter Reagents, Cuvettes, Disposable Tips, water, Wash Buffer, maintenance liquid); incubator, wash station, reader, and a barcode reader for reagents and samples. Installation of the LIAISON® XL Workcell Upgrade Kit allows the LIAISON® XL Analyzer to be used with a compatible LAS and extends the sample pipetting capabilities to a point-in-space located external to the analyzer.

COMPARISON TO PREDICATE DEVICE:

The following table compares the LIAISON® XL Analyzer to the LIAISON® XL Workcell Upgrade Kit.

Summary of Device Similarities and Differences:

Characteristic	Predicate Device LIAISON® XL analyzer	New Device: LIAISON® XL with LIAISON® XL Workcell Upgrade Kit
FDA k#	K103529	K141116
Intended Use	The LIAISON® Anti-HAV assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients. This assay is not intended for screening blood or solid or soft tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing assay performance characteristics in these populations. Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician. The LIAISON® XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for *in vitro* diagnostic analysis of CLIAs on human serum or plasma. The system menu includes infectious disease, bone and mineral, and endocrinology CLIAs. It is to be used only with FDA cleared chemiluminescence immunoassays that are marketed by DiaSorin for the LIAISON® XL Analyzer. The LIAISON® Control Anti-HAV (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Anti-HAV assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON® and LIAISON® XL.	The LIAISON® Anti-HAV assay is an *in vitro* chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients. This assay is not intended for screening blood or solid or soft tissue donors. Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients. The user is responsible for establishing assay performance characteristics in these populations. Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician. The LIAISON XL Analyzer is an automated discrete continuous loading chemiluminescent immunoassay (CLIA) analyzer for in vitro diagnostic analysis of CLIAs on human specimens cleared for use on the analyzer. It is only to be used with FDA cleared chemiluminescent immunoassays that are marketed by DiaSorin for the LIAISON XL Analyzer. The analyzer can be connected to a third party Laboratory Automation System (LAS) which has been previously cleared for use with FDA cleared assays. The LIAISON® Control Anti-HAV (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Anti-HAV assay. The performance characteristics of LIAISON® controls have not been established for any other assays or instrument platforms different from LIAISON®, LIAISON® XL and LIAISON® XL with LIAISON® XL Workcell Upgrade Kit.
Principles of Operation	Chemiluminescence using magnetic particle solid phase and chemiluminescent tracer	Same

Characteristic	Predicate Device LIAISON® XL analyzer	New Device: LIAISON® XL with LIAISON® XL Workcell Upgrade Kit
FDA k#	K103529	K141116
Optical System	High-sensitive, low-noise photomultiplier tube (PMT) operating as an ultra-fast photon counter. Pulses are amplified by a rapid electronic amplifier.	Same
	Circuit that suppresses PMT signal noise.	Same
	Linear measuring range: 300 – 650 nm	Same
	Light peak of chemiluminescence emitted at 450 nm	Same
Temperature Control	▪ Reaction Temperature: 36°C ± 1°C ▪ Reagent Storage Temperature: 11-15°C	Same Same
Dispense System	▪ Automated pipetting of samples and reagents; ▪ Left pipetting unit used for samples (using disposable tip); ▪ Right pipetting unit used for reagents (metal needle);	Same
	Precision syringes (sample and reagent)	Same
	Sample Probe (disposable tip): ▪ Liquid Level Detection and Clot Detection feature (pressure) ▪ Disposable tips: 6 trays of 96 tips each can be loaded on board. ▪ Monitored through software counter and presence sensor upon tip pick-up. ▪ Re-loading allowed during run	Same

Characteristic	Predicate Device LIAISON® XL analyzer	New Device: LIAISON® XL with LIAISON® XL Workcell Upgrade Kit
	Reagent Probe: ▪ Liquid Level Detection (capacitive), with software tracking of reagent level ▪ Optical Liquid Verification (real-time monitoring of liquid flow inside the probe)	Same
Sample Handling	Capacity: ▪ Holds 10 sample racks, ▪ 12 places per rack	Same (in the stand alone mode)
	Tube types: ▪ primary tube ▪ aliquot tube ▪ pediatric	Same
	Sample presence, sample type (calibrator, control, patient), tube size, and processing completion tracked by operating software and sample bar-code	Same (in the stand alone mode)
Test Orders	From LIS or middleware to analyzer	Same
Test Results	To LIS or middleware from analyzer	Same
Reagent Handling	Capacity: 25 Reagent Integrals (RI), plus 4 positions for Ancillary Reagents	Same
	RI contains all reagents required for any given assay (up to 7 vials per RI, first vial always contains magnetic particles).	Same

	Assay-specific processing and analysis parameters, calibration, lot number, expiration date, and usage (number of tests run) are controlled by operating software as communicated by RF-Tag	Same
Additional Reagents	▪ Control Set (2-3 levels) ▪ LIAISON Light Check (diagnostic tool only) ▪ LIAISON Starter Kit (Starter Reagents 1 and 2) ▪ LIAISON Wash/System Liquid (used as a wash liquid only – immunometric wash step) ▪ Purified water is also required as System Liquid, as fluidic filler and to perform: o reagent needle cleaning o washer needle cleaning ▪ A cleaning tank is available to host a cleaning liquid suitable for automated maintenance purpose	Same
	Level sensing by capacitive rod	Same
Starter Reagents	Recognition of Starter Reagents via RF-Tag	Same
	Two bottles of each Starter Reagent can be loaded on board	Same
	Injection of Starter Reagents through high precision/accuracy pump (fixed dispensing volume)	Same
	Dispense monitoring through optical sensor	Same
	Injection of Starter Reagents occurs at controlled temperature (33-37°C)	Same

Characteristic	Predicate Device LIAISON® XL analyzer	LIAISON® XL Workcell Upgrade Kit
Reaction Modules	Single-cavity Cuvettes	Same
	Storage capacity: >600 Cuvettes	Same
	Inventory monitoring through software counter. Sensors detect actual presence of Cuvettes	Same
	Reloading allowed during run	Same
	Unloading automatic into waste bag	Same
Test Processing	Random Access and Batch	Same
	Continuous operation	Same
	Sample scheduling optimized throughput process	Same
Assay Protocols	1-Step assays: 1 incubation sequence / 1 wash sequence; average incubation time = 10 minutes	Same
	2-Step assays: 2 incubation sequence / 1 or 2 wash sequence(s); average incubation time = 10 minutes	Same
	Two-point calibration of assays	Same
Human Interface	Computer	Same
	Touch-screen On Screen Keyboard (keyboard and mouse not supplied)	Same
	Monitor – touch screen, color	Same
	Printer	Same
	Stationary barcode scanner for identification of samples	Same (in the stand alone mode)
	Stationary RF-Tag reader for identification of reagents (Reagent Integrals and Starter Reagents)	Same
	Handheld barcode scanner for identification of controls	Same
Data Analysis	Automated data reduction	Same
	Assay-specific Master Curve with 2-point recalibration	Same
	Assay-specific data reduction	Same
QC Software	Stored lot-specific control results	Same
	Lot-specific Levey-Jennings plotting	Same
	Trend identification	Same
	Statistical analyses	Same
Specimens	Serum or plasma	Same
	Sampling from primary, aliquot, or pediatric tubes	Same
Disposables	Reagent Integrals	Same
	Light Check (diagnostic tool)	Same
	Starter Kit	Same
	Wash/System Liquid	Same
	Cuvettes	Same
	Disposable Tips	Same
	Waste Bag	Same
Software	▪ Based on: Windows Vista ▪ Software controlling the analyzer with Graphical User Interface (v4.0.0.4 sp3) ▪ LAS interface disabled	▪ Same ▪ Same ▪ LAS interface enabled

Characteristic	Predicate Device LIAISON® XL analyzer	LIAISON® XL Workcell Upgrade Kit
General Operation	The Cuvette sorting mechanism feeds the incubator, in order to have all vacant incubator positions (i.e. 80 incubation slots) always full of Cuvettes available for new pipetting tasks. Pipetting of sample and reagents occurs within the incubator.	Same
General Operation	Incubator rotates (CW/CCW) in order to bring the appropriate Cuvette to one of the 3 dedicated pipetting positions. At the end of the incubation time, the incubator-washer pusher transports the Cuvette from its position in the incubator into the washer. The washer transport mechanism (spindle) moves the Cuvettes present in the washer channel one cavity position at a time, using half of the analyzer time cycle, from one washing station to the next. Each of the 6 washer needles accesses a Cavity only once. Upon completion of the wash step, the following two situations may apply: CASE 1: Return transport for 2-step process. The washer- incubator pusher moves the Cuvette back into the incubator (in a vacant incubator slot) for addition of second-step reagent(s). After incubation, the Cuvette goes through the washer again. CASE 2: Transport into the measuring chamber. The washer transport mechanism (spindle) moves the Cuvette to the measuring chamber. After the measurement, the reaction solution is removed by suction and the Cuvette then is transported out of the measuring chamber and into the solid waste bin.	Same

Table 2: Differences

Characteristic	Predicate: LIASON XL Analyzer K103529 LIAISON® XL	New Device: LIASON XL with LIASON XL Workcell Upgrade Kit K141116
Sample Aspiration	Directly from sample tube in the sample bay of the analyzer	▪ Directly from sample tube in the sample bay of the analyzer (in the stand alone mode) and ▪ Directly from sample tube presented by the Workcell to the aspiration point-in-space position at the analyzer interface (in LAS mode)
Sample Identification from bar-coded tubes	Bar-coded sample tubes (mono dimension barcode) read directly by analyzer bar code reader	▪ Bar-coded sample tubes (mono dimension barcode) read directly by analyzer bar code reader (stand-alone mode) and ▪ Bar-coded sample tubes (mono dimension barcode) read by Workcell barcode scanner.
LAS Communication	N/A	LIAISON® XL software communicates with Workcell via LAS interface communication protocol

CONCLUSION:

The results from the non-clinical studies submitted in this premarket notification demonstrate that the LIAISON® XL Workcell Upgrade Kit is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Center – WO66-G609
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July 25, 2014

Re: K141116
Trade/Device Name: LIAISON XL Analyzer with LIAISON XL Workcell Upgrade Kit
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A virus (HAV) serological assays
Regulatory Class: II
Product Code: LOL, JJF
Dated: April 29, 2014
Received: April 30, 2014

Dear Ms. Meyer:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141116

Device Name
LIAISON XL Analyzer

Indications for Use *(Describe)*
The LIAISON® Anti-HAV assay is an in vitro chemiluminescent immunoassay intended for the qualitative detection of total antibodies to hepatitis A (anti-HAV) in human serum and sodium heparin plasma samples using the LIAISON® Analyzer family. The assay is indicated as an aid in the laboratory diagnosis of current or previous HAV infections in conjunction with other serological and clinical information and to determine the presence of an antibody response to HAV in vaccine recipients.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stephen J. Lovell -S
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