DiaSorin Inc.
Mari Meyer
Vice President, Regulatory and Clinical Affairs, North America
1951 Northwestern Ave
Stillwater, Minnesota 55082

Re: K193532
Trade/Device Name: Liaison Anti-HAV
Regulation Number: 21 CFR 866.3310
Regulation Name: Hepatitis A Virus (HAV) Serological Assays
Regulatory Class: Class II
Product Code: LOL, JJE
Dated: December 17, 2019
Received: December 20, 2019

Dear Mari 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maria Garcia, Ph.D.
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193532

Device Name
LIAISON® Anti-HAV

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.

The assay is not intended for screening blood or solid or soft tissue donors.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	LIAISON® Anti-HAV
Common Names/Descriptions:	Hepatitis A Virus (HAV Serological Reagents)
Classification Names:	Hepatitis A Test (Antibody and IgM Antibody)
Product Code:	LOL

PREDICATE DEVICES

LIAISON® Anti-HAV
Reference K082049

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.

DESCRIPTION:

The method for qualitative determination of anti-HAV is a competitive sandwich chemiluminescence immunoassay (CLIA) based on neutralization. The assay uses magnetic particles (solid phase) coated with IgG antibodies to HAV (mouse monoclonal), and a mouse monoclonal anti-HAV antibody conjugate linked to an isoluminol derivative (isoluminol-antibody conjugate). The first incubation step consists of adding the HAV antigen to calibrators, samples or controls, during which anti-HAV present in calibrators, samples or controls binds to a fixed and limited amount of HAV, thus forming an HAV-anti-HAV immune complex. After this step the second incubation follows and it involves addition of magnetic microparticles and conjugate into the cuvette, during which the antibody conjugate and the solid-phase antibody compete with

anti-HAV present in the specimen for HAV. This allows the conjugate to bind to the solid phase and to form a sandwich. If all HAV added is sequestered in an HAV-anti-HAV immune complex during the first incubation, no sandwich is formed during the second incubation. After the second incubation, the unbound material is removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is inversely indicative of anti-HAV present in calibrators, samples or controls.

PERFORMANCE DATA:

METHOD COMPARISON WITH PREDICATE DEVICE:

The agreement study consisted of testing 100 frozen serum samples on the LIAISON® XS and the LIAISON® XL Analyzers with the LIAISON® Anti-HAV Assay. The samples were either selected or prepared by DiaSorin Inc. to reach different levels of anti-HAV antibody. They were randomly divided among three (3) sites for testing. LIAISON® XS testing was performed at 2 external sites and at DiaSorin Inc., with the LIAISON® XL Analyzer testing performed internally at DiaSorin Inc. The categorical agreement results are presented in the following table.

Agreement Study Results

	LIAISON® XL Analyzer						
LIAISON® XS® Analyzer	Eqv	High Neg	High Pos	Low Pos	Mod Pos	Neg	Grand Total
High Neg	-	23	-	-	-	1	24
High Pos	-	-	23	-	2	-	25
Low Pos	1	-	-	13	2	-	16
Mod Pos	-	-	-	4	14	-	18
Eqv	1	-	-	2	-	-	3
Neg	-	1	-	-	-	13	14
Grand Total	2	24	23	19	18	14	100

Negative Agreement: 97.4% (38/39) 95% CI: 86.8% to 99.5%
Positive Agreement: 96.7% (58/60) 95% CI: 88.6% to 99.1%
Overall Agreement: 97.0% (96/99) 95% CI: 91.5% to 99.0%

REPRODUCIBILITY:

A 12 day precision/reproducibility study was conducted internally at DiaSorin Inc. and at two (2) external sites to verify the precision of the LIAISON® XS Analyzer with the LIAISON® Anti-HAV Assay, with one (1) lot of LIAISON® Anti-HAV (#310200) and one (1) lot of LIAISON® Control Anti-HAV (#310201). One (1) LIAISON® XS Analyzer was used for testing at each site and at least two (2) operators performed the testing at each site.

A coded precision panel was used in this study, consisting of seven (7) serum specimens manufactured by DiaSorin S.p.A. and two (2) kit controls (a positive and negative from a single control lot). All precision panel samples (n=7) were stored at -20°C or lower prior to testing and Positive and Negative kit controls were handled according to the Instructions for Use.

Each day for 12 days a single run of four replicates was generated by a single operator for each member of the precision panel which included seven (7) samples and two (2) kit controls for a total of 48 replicates at each site per sample.

The mean, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens for each of the sites and across sites. The within-Day results were used to calculate the assay's repeatability and the between-Day results were used to calculate the assay's reproducibility.

Results

The 12-day Index results are summarized in the following (combined sites). The %CVs are computed for repeatability (within day), between day and within laboratory, between laboratory and reproducibility (total) precision.

12-Day Precision Study Results (3 sites)

Sample Description	Mean	N	Repeatability (within Day)		Between Day		Between Laboratory		Reproducibility (Total)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	175186*	144	3012	1.7%	6194	3.5%	3757	2.1%	7846	4.5%
Positive Control	0.43	144	0.011	2.4%	0.020	4.7%	0.020	4.6%	0.030	7.0%
Sample 1	0.23	144	0.005	2.1%	0.010	4.6%	0.011	5.0%	0.016	7.1%
Sample 2	0.48	144	0.008	1.8%	0.029	6.0%	0.000	0.0%	0.030	6.3%
Sample 3	0.51	144	0.008	1.6%	0.021	4.2%	0.012	2.3%	0.026	5.1%
Sample 4	0.91	144	0.015	1.7%	0.049	5.3%	0.032	3.5%	0.060	6.6%
Sample 5	2.09	144	0.026	1.3%	0.085	4.1%	0.025	1.2%	0.092	4.4%
Sample 6	1.71	144	0.026	1.5%	0.105	6.2%	0.004	0.2%	0.108	6.3%
Sample 7	0.94	144	0.018	1.9%	0.035	3.7%	0.041	4.3%	0.057	6.0%

**Dose was above the reading range of the assay. Precision calculations are based on signal (RLU) for this sample.*

CONCLUSION:

The material submitted in this premarket notification is complete and supports a substantial equivalence decision. The labelling is sufficient and it satisfies the requirements of 21CFR 809.10