July 27, 2018

LIA Diagnostics
Anna Couturier
Official Correspondent
1015 Chestnut St
Suite 1401
Philadelphia, Pennsylvania 19107

Re: K171136
Trade/Device Name: LIA Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: October 23, 2017
Received: October 23, 2017

Dear Anna Couturier:

This letter corrects our substantially equivalent letter of November 20, 2017.

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 Part

801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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)*

K171136

Device Name

Lia Pregnancy Test

Indications for Use *(Describe)*

Lia Pregnancy Test is intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

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.

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LIA Diagnostics
1015 Chestnut Street
Suite 1401
Philadelphia, PA 19107

510(k) SUMMARY
For k171136
Lia Pregnancy Test

Submitter Information:

LIA Diagnostics, Inc.
1015 Chestnut Street
Suite 1401
Philadelphia, PA 19107

Contact Person:
Anna Couturier
Telephone Number: 717-799-7795

Date Prepared: November 17, 2017

Device Name:

Proprietary Name:
Classification Name: Kit, test, pregnancy, hCG, over-the-counter
Common Name: Lia Pregnancy Test
CFR Number: 21 CFR 872.1155
Device Class: II
Product Code: LCX

Predicate Device:

Predicate Device Name	510(k)	Company Name
OSOM hCG Urine Test	k9741 59	Sekisui Diagnostics

Table 1. Predicate device information

Description of Device:

The Lia Pregnancy Test is an *in vitro* diagnostic device for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

The method employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify hCG in the test samples. The sensitivity of the test has been adjusted to 22mIU/mL. The Lia Pregnancy

Test is a lateral flow chromatographic immunoassay. When a mid-stream urine sample is applied to the absorbent end, the sample enters the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta hCG monoclonal antibody), flowing across the pre-coated (Goat anti-alpha hCG polyclonal antibody) membrane. During the test, hCG in the urine specimen reacts with the dye conjugate and forms a complex. The complex migrates along the cellulose strip to the α-hCG antibody line (T), and remains captured in the T line. As a result, a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The control line develops in the Control (C) zone regardless of the result.

Indications for Use:

Lia Pregnancy Test is intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

The Lia Pregnancy Test is intended for Over-the-Counter use.

Identification of Risk Analysis Method

Risk analysis was performed on the Lia Pregnancy Test utilizing an FMEA process based on ISO 14971:2012. The results of the risk analysis performed on the Lia Pregnancy Test concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, usability and performance testing were performed to mitigate other potential risks.

Substantial Equivalence:

ELEMENT	PROPOSED DEVICE: Lia Pregnancy Test	PREDICATE DEVICE: OSOM hCG Urine Test	DIFFERENCES WITH PREDICATE DEVICE
510(k)	k171136	k974159	
Indications for Use	Lia Pregnancy Test is indicated for use intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.	For the qualitative determination of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy.	Predicate intended for POC (point-of-care).

Specimen	Urine	Urine	Same
Methodology	Immunochromatographic Assay	I mmunochromatographic Assay	Same
Time to Result	5 minutes	5 minutes	Same
Analytical Sensitivity	25mIU/mL	25mIU/mL	Same
Results	Qualitative	Qualitative	Same
Material Composition	• Assay substrate – One contiguous cellulose web for sample pad, conjugate pad, test strip and absorbent wick • Antibody – Mouse monoclonal, goat polyclonal	• Cover - plastic • Assay substrate – Cellulose sample collection pad, glass fiber conjugate pad, nitrocellulose test strip, cellulose absorbent wick • Antibody – mouse monoclonal, rabbit polyclonal	Membrane material of Lia is cellulose, not nitrocellulose, like the membrane of the predicate. Both substrates are inert and do not affect the test results.
Material Compatibility	Biocompatibility meets requirements	Biocompatibility meets requirements	None
Target population	Traditional and normal females for determination of pregnancy	Traditional and normal females for determination of pregnancy	Same
Device design	Handheld, mid-stream design. Lateral flow test strip housed inside a hydrophobic cellulose housing with a viewing window for results interpretation.	Lateral flow dipstick test strip	
Performance	Use friendly interface, easy to operate	Use friendly interface, easy to operate	
Sterility	Device provided non-sterile	Device provided non-sterile	
Chemical Safety	There are no hazardous chemicals contained within this kit at	There are no hazardous chemicals contained within this kit at	

	concentrations that are considered hazardous to personal health and/or the environment.	concentrations that are considered hazardous to personal health and/or the environment.	
Compatibility with environment and other devices	The system is used inside buildings. Interaction with other devices is not performed	The system is used inside buildings. Interaction with other devices is not performed	
Used at:	Home	Point of care	
Weight	2.125g	.29 g	
Dimensions, housing (cm.) HxWxL	.38 x 5.5 x 15.5	N/A	Predicate is a test strip only
Dimensions, test strip (cm. HxWxL)	.035 x 3.7 x 17.5	10 x .4 x .1	
Operating temperature	+59°F to +93°F (+15°C to +34°C)	+59°F to +86°F (+15°C to +30°C)	
Humidity	Operating, 20-76%	Operating, 15% to 75%	
Storage temperature	59F to 86F (1 5C to 30C),in foil pouch	59F to 86F (1 5C to 30C),	
Technology Principle	dyed lateral-flow immunoassay	dyed latex-based lateral-flow immunoassay	
Format	Cassette (non-plastic)	Dipstick	
Results	Qualitative	Qualitative	
Results Interpretation	Visual	Visual	
Specimen Type	Human urine	Human urine	
Specimen Application	Mid-stream	Dipstick	
Cut-off Value	25 mIU/ml	25 mIU/ml	
Traceability	WHO International Standard #5	WHO International Standard #3	
Quality Control	Built-in, internal control	Built-in, internal control	
Shelf-life	18 months	18 months	

Table 2. Substantial equivalence

Differences			
	Lia Pregnancy Test	**Predicate Device**	
Test Format	Mid-stream format	Dipstick format	
Test strip composition	One contiguous piece of cellulose	Cellulose sample collection pad, glass fiber conjugate pad, nitrocellulose test strip	
Used at	Home	Point-of-Care	

Table 3. Differences between the Lia Pregnancy Test and legally marketed predicate

Minor differences exist between the Lia Pregnancy Test and the predicate device. The only differences are in the housing material and membrane of the test strip, neither of which affect the immunochromatographic results. These minor differences do not impact substantial equivalence of the Lia Pregnancy Test.

The Lia Pregnancy Test**,** and the predicate device, OSOM hCG Urine Test (K9741 59) use the same chemistry with essentially the same test design.

Non-Clinical Performance Data:

Because the proposed device, Lia Pregnancy Test**,** and the predicate device, OSOM hCG Urine Test (K9741 59) use similar materials with essentially the same test design, new biocompatibility testing or clinical testing was not required for the device to support substantial equivalence

Performance testing focused on verification of performance, and safety of the Lia Pregnancy Test. Below is a list of the standards to which testing was performed:

- Precision/Reproducibility
  - To determine the reproducibility of the Lia Pregnancy Test using a 12-member hCG-spiked urine panel tested by multiple operators over multiple, non-consecutive days. The Lia Pregnancy Test exhibited reproducibility of results (sero-negative and hCG sero-positive members) across a multi-kit lot, multi-operator and multi-day study.
- Cross-reactivity
  - To determine if the Lia Pregnancy Test was affected (i.e. cross-reacted) by a relevant challenge dose of closely-related human lutieinzing hormone (hLH), human follicle stimulating hormone (hFSH) or human thyroid stimulating hormone (hTSH). Neither hLH, hFSH nor hTSH affect the correct call of sero-negative and hCG sero-positive urine samples in the Lia Pregnancy Test.

- Interfering Substances
  - To determine if the Lia Pregnancy Test was affected by potentially interfering substances which may be found in human urine. The study assessed interference on both sero-negative and hCG sero-positive samples. The presence of a wide array of potentially interfering substances which could be found in human urine failed to affect the correct call rates of sero-negative and hCG sero-positive samples on the Lia Pregnancy Test.
- Limit of Detection
  - To determine the limit of detection (LoD) of the Lia Pregnancy Test using WHO #5 reference material. The Lia Pregnancy Test exhibited 100% detection of WHO #5 hCG-spiked samples at 22 and 25 mIU/ml and detected 50% of hCG-spiked samples with concentrations at 14 mIU/ml
- Stability/Shelf Life
  - To investigate the Lia Pregnancy Test device's stability, the product was stored at ambient (anticipated end-user storage conditions) and thermal-stress conditions (37 °C and 50 °C) and tested against a panel of pedigreed urine samples. Data supports an 18-month shelf life claim
- Effects of Urine pH
  - To determine if the performance of the Lia Pregnancy Test was affected by the pH of urine samples. Performance of the Lia Pregnancy Test is not affected by pH of the urine sample.
- Effects of Urine Specific Gravity
  - To determine if the performance of the Lia Pregnancy Test was affected by the specificity gravity of urine samples. The normal range for specific gravity of urine is 1 .003 to 1 .036. In this study, performance of the Lia Pregnancy Test was not affected by the specific gravity of the urine samples, either above or below, the normal range
- High Dose Hook Effect (aka prozone)
  - To determine if the Lia Pregnancy Test exhibits evidence of prozone (aka "hook effect") behavior when challenged with a high concentration of analyte (hCG). In immunoassay tests which have prozone issues, false negative results could be reported despite the analyte being present in the sample. Results show the Lia Pregnancy Test does not exhibit prozone activity from 25 to 500,000 mIU/ml concentrations of hCG.
- Beta hCG Core Fragment Reactivity testing
  - To determine how the Lia Pregnancy Test how was affected by the beta-core fragment of hCG, a hCG-like molecule which may be present at high concentrations during pregnancy. The Lia Pregnancy Test detects βhCGcf at concentrations >1000 pmol/L and detects low- and high-titer intact hCG even when βhCGcf is present.

Along with the above tests, Stability of results, shipping stability, and environmental factors testing were also conducted and demonstrated compliance to specifications.

The results of these performance tests support the substantial equivalence of the proposed device, Lia Pregnancy Test**,** with the predicate device, OSOM hCG Urine Test (K974159)

Clinical Performance Data.
Professional evaluations were conducted considering the proposed device intended use, intended users, and intended use environments.

All studies were completed by lay-users and professional staff members at 4 women's health clinics. Lia performed two studies with 174 lay-user consumers between the ages of 18 – 49 to determine lay-person usability. In each study, devices from three manufacturing lots of Lia tests were used.

For the Lia Clinical Study, a total of N=1 53 women, attending four different women's health clinics, self-performed the Lia Pregnancy Test according to Package Insert instructions. Approximately half of the subjects were suspected to be pregnant. Lay-users collected a mid-stream sample on the Lia Pregnancy Test and a small aliquot in a specimen cup. The later sample was tested with the predicate device in clinical lab by a professional. The lay-user recorded their interpretation of the Lia Pregnancy Test results and then a clinical staff member examined and reported their interpretation of Lia Pregnancy Test results. Samples were randomly collected at various times throughout the day. Ages of these women ranged from 18 to 49 years.

The conformity between the user interpretation of the Lia Pregnancy Test and the staff interpretation of the Lia Pregnancy Test is 98.7%. The conformity between the staff interpretation of the Lia Pregnancy and the standard of care is 100%.

Data analysis shows that lay-users can successfully interpret the results, and that the test results were 100% concordant with the standard of care. In the post test questionnaire users report that the test is easy to use and the instructions are easy to understand. In the questionnaire answered after subjects used the test, 98% of lay-users said that the printed instructions were clear and usable. 91% of participants were confident that they had performed the test correctly. 98% said it was easy to use the test.

In an additional lay user study, 15 women performed simulated mid-stream tests with samples provided by Lia at defined hCG concentrations, close to the cutoff. In this study, 15 lay-users tested three different samples (2, 33, and 100mIU/mL) on three different lots of the Lia Pregnancy Test. Users were "blinded" as to sample status, and recorded their interpretation of the results. 100% of users correctly identified positive and negative results.

As a result of clinical usability validations involving performance testing, data was gathered to support our assessment that the risk of harm has been adequately mitigated and no unacceptable risks or unacceptable use related hazards related to the Lia Pregnancy Test were identified.

Conclusion Regarding Substantial Equivalence

The proposed device, Lia Pregnancy Test**,** is a pregnancy test for over-the-counter use intended for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy. The Lia Pregnancy Test has the same intended use, incorporates the same fundamental technology as the predicate, uses similar material and has essentially the same design as the predicate device, OSOM hCG Urine Test (K974159)

Test data to verify the performance of the proposed device, Lia Pregnancy Test**,** has been provided including:

- Precision/Reproducibility
- Cross-reactivity
- Interfering Substances
- Limit of Detection
- Stability/Shelf Life
- Effects of Urine pH & Urine Specific Gravity
- High Dose Hook Effect
- Beta hCG Core Fragment

The results of this performance testing, combined with the design and intended use comparison with the predicate device, OSOM hCG Urine Test (k974159), support substantial equivalence to, the predicate device, OSOM hCG Urine Test (k974159).