January 17, 2020

Shenzhen New Industries Biomedical Engineering Co., Ltd
℅ Joe Shia
Director
LSI International Inc
504E Diamond Ave., Suite F
Gaithersburg, MD 20877

Re: K192547
Trade/Device Name: MAGLUMI 2000 HCG/β-HCG
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: DHA
Dated: December 6, 2019
Received: December 10, 2019

Dear Joe Shia:

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,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology 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)*
k192547

Device Name
MAGLUMI 2000 HCG/β-HCG

Indications for Use *(Describe)*
MAGLUMI 2000 HCG/β-HCG is an in vitro chemiluminescence immunoassay for the quantitative determination of total beta human chorionic gonadotropin (total β-hCG) in human serum. The measurement of total β-hCG is used as an aid in the early detection 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K192547

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1. Date: January 17, 2020

2. Submitter: Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.16, Jinhui Road, Pingshan New District, Shenzhen
China 518122

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: MAGLUMI 2000 HCG/β-HCG

Classification: Class II (assay)

Product Code	CFR #	Product Name
DHA	862.1155	Human Chorionic Gonadotropin (HCG) Test System

5. Predicate Devices:
K130020, Beckman Access Total β-HCG (5th IS) Assay

6. Device Description:

MAGLUMI 2000 HCG/β-HCG kit consists of the following reagents:
Magnetic Microbeads- coated with anti-HCG monoclonal antibody, containing BSA, NaN3 (<0.1%)
Calibrator Low-Containing BSA and HCG antigen, NaN3(<0.1%)
Calibrator High- Containing BSA and HCG antigen, NaN3(<0.1%)
Buffer- containing BSA, NaN3 (<0.1%)
ABEI Label- Anti-HCG monoclonal antibody labeled with ABEI, containing BSA, NaN3 (<0.1%)
Control 1- Containing BSA and HCG antigen, NaN3 (<0.1%)
Control 2- Containing BSA and HCG antigen, NaN3 (<0.1%)

7. Intended Use:
MAGLUMI 2000 HCG/β-HCG is an in vitro chemiluminescence immunoassay for the quantitative

determination of total beta human chorionic gonadotropin (total β-hCG) in human serum. The measurement of total β-hCG is used as an aid in the early detection of pregnancy.

8. Standard/Guidance Documents
   Clinical and Laboratory Standards Institute EP5-A2 – Evaluation of Precision Performance of Clinical Chemistry Devices-Approved Guideline-Second Edition.
   Clinical and Laboratory Standards Institute EP6-A – Evaluation of the Linearity of Quantitative Analytical
   Clinical and Laboratory Standards Institute EP17-A2: Evaluation of detection Capability for Clinical Laboratory Measurement Procedures
   Clinical and Laboratory Standards Institute EP7-A2 – Interference Testing in Clinical Chemistry
   Clinical and Laboratory Standards Institute EP9-A2 – Method Comparison and Bias Estimation Using Patient Samples

9. Substantial Equivalence Information

Assay Similarities

Item	Predicate Device	Candidate Device
Intended Use/ Indication for Use	For the quantitative determination of human chorionic gonadotropin (β-subunit) (HCG/β-HCG) in human serum using UniCel DxI chemiluminescence immunoassay analyzer. The measurement of HCG/β-HCG is used in the early detection of pregnancy.	Same
Test principle	Sandwich Immunoassay	Same
Measurement	Quantitative	Same
Traceability	WHO 5th International Standard 07/364	Same
Automated	Yes	Same

Assay Differences

Item	Predicate Device	Candidate Device
Specimen	Serum or Plasma	Serum
Measuring range	0.6 – 1350 mIU/mL up to 270,000 mIU/mL with sample dilution	1.132-4680 mIU/mL
Capture antibody	Paramagnetic particles coated with goat anti-mouse IgG: mouse monoclonal anti-βhCG complexes	Magnetic microbeads coated with anti-HCG monoclonal antibody

Detection	Rabbit anti-βhCG alkaline phosphatase conjugate	ABEI-labeled Anti-HCG monoclonal antibody
Sample size	25 ul	15 ul
Calibration	Utilizes a stored calibration curve	2 points
Calibrator	6 levels	Calibrator Low and Calibrator High

10. Test Principle

The HCG/β-HCG assay is an in vitro chemiluminescence immunoassay using FDA previously cleared MAGLUMI 2000 instrument (k162698). The assay is a sandwich chemiluminescence immunoassay.

The sample (or calibrator/control, if applicable), magnetic microbeads coated with anti-HCG monoclonal antibody are mixed thoroughly and incubated at 37°C to form immuno complexes, and then perform a wash cycle. After addition of ABEI labeled with anti-HCG monoclonal antibody, the complexes bound to the monoclonal antibody and incubate to form sandwich complexes. After precipitation in a magnetic field, decant the supernatant, and then perform another wash cycle. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier within 3 seconds as relative light units (RLUs), which is proportional to the concentration of HCG/β-HCG present in the sample (or calibrator/control, if applicable).

11. Performance Characteristics

1. Analytical Performance

a. Precision

The precision was determined using the CLSI EP5-A3 protocol as a guide. The study was conducted on three different instruments with three controls, two calibrators, and 6 native patient serum pools. The data was collected over 20 days in duplicate with 2 runs per day with a total of 80 samples analyzed per level on each instrument. The results (in mIU/mL) obtained are summarized in the following tables:

Sample	Mean (mIU/mL)	Within-Run		Between-Run		Between-Day		Total (within instrument)		Reproducibility (across instruments)	
	(N=240)	SD	CV%	SD	CV%	SD	CV%	SD	CV%	SD	CV%
Control 1	5.023	0.226	4.50	0.099	1.97	0.205	4.08	0.321	6.39	0.326	6.49
Control 2	37.135	1.529	4.12	0.814	2.19	1.282	3.45	2.155	5.80	2.250	6.06
Control 3	300.135	10.737	3.58	7.666	2.55	10.332	3.44	16.757	5.58	17.665	5.89
Calibrator low	2.876	0.199	6.92	0.052	1.81	0.154	5.35	0.257	8.94	0.277	9.65
Calibrator high	1722.515	47.252	2.74	43.649	2.53	53.789	3.12	83.853	4.87	92.799	5.39
Native serum pool 1	1.889	0.137	7.25	0.040	2.12	0.101	5.35	0.175	9.26	0.185	9.79
Native serum pool 2	13.625	0.573	4.21	0.370	2.72	0.527	3.87	0.862	6.33	0.868	6.37
Native serum pool 3	103.65	3.796	3.66	2.664	2.57	3.710	3.58	5.939	5.73	6.377	6.15
Native serum pool 4	770.936	25.801	3.35	21.293	2.76	19.638	2.55	38.791	5.03	42.931	5.57
Native serum pool 5	2443.443	80.459	3.29	53.257	2.18	64.944	2.66	116.309	4.76	126.735	5.19
Native serum pool 6	4555.709	107.024	2.35	96.600	2.12	102.452	2.25	176.868	3.88	198.324	4.35

b. Linearity

The linearity of the MAGLUMI HCG/β-HCG method was determined following the CLSI EP6-A procedure. Linearity samples were prepared by mixing high level samples and low level samples through different volume ratios to span the whole measuring range with HCG/β-HCG concentrations from 0.3 to 4680 mIU/mL. Each sample was measured in quadruple on 3 lots of reagent. Linearity was evaluated using regression analysis based on CLSI EP6-A.

The assays are linear between 1.134 and 4680 mIU/mL with the following relationship:
Observed = 1.0243 (Expected) – 54.935, $R^2 = 0.9932$

c. Stability

Accelerated stability study at 37ºC showed that all controls are stable for 12 months at 2-8ºC. Accelerated stability study at 37ºC showed all that calibrators are stable for 12 months at 2-8ºC. Accelerated stability study at 37ºC showed that the reagent is stable for 12 months at 2-8ºC. The real time stability at 2-8ºC is on-going.

d. Detection Limit

Detection limit studies were performed following CLSI EP17-A guidelines.
The limit of blank (LOB) is the 95th percentile value from 80 measurements of HCG/β-HCG negative serum samples using 3 different lots of HCG/β-HCG reagents over 5 days. The LOB corresponds to the concentration below which analyte-free samples are found with a probability of 95% and was determined to be 0.302 mIU/mL (highest of the 3 lots).
The limit of detection (LOD) is determined based on the LOB and the standard deviation of low concentration samples. The LOD corresponds to the lowest analyte concentration which can be detected. Four level of low samples were measured in 80 replicates over 5 days per sample using 3 lots of reagents. LOD was determined to be 0.471 mIU/mL (highest of the 3 lots).
The limit of quantitation (LOQ) was determined by measuring six low serum samples, in six replicates per run, one run per day, over 5 days, using 3 lots of reagents. LOQ is defined as the lowest analyte concentration that can be reproducibly measured with percent bias no more than 15% and CV% no more than 20% and was determined to be 1.134 mIU/mL (highest of the 3 lots).

e. Interference

A interference study was performed using two base serum samples containing HCG/β-HCG of 6.0 mIU/mL and 100 mIU/mL respectively. These samples were spiked with various cross reactants and measured for these solutions using 3 lots of reagents. The

following table shows interference of potential interference substances.

Substances	Highest concentration tested without significant interference
TSH	1000 mIU/L
LH	500,000 mIU/L
FSH	500,000 mIU/L
hGH	25,000 mIU/L
hCG α-subunit	500,000 mIU/L

The effect of endogeous substances were evaluated using human serum pools. For each substance, three serum samples containing 6.0 mIU/mL, 100 mIU/mL and 2000 mIU/mL concentration of HCG/β-HCG were analyzed, the highest concentration of interferents were listed below at which no significant interference was observed.

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Conjugated bilirubin	60
Unconjugated bilirubin	42.5
Hemoglobin	1000
triglyceride	2000

The effect of common drugs and interference substances were evaluated using human serum pools. For each substance, three serum samples containing 6.0 mIU/mL, 100 mIU/mL and 2000 mIU/mL concentration of HCG/β-HCG were analyzed. For all substances tested, no significant interference was defined as recovery ± 10% of initial value. The substances and the highest concentration tested which did not cause significant interference are listed below.

Potential Interferent	Highest concentration tested at which no significant interference is observed (mg/dL)
Cefoxitin	680
Ethanol	790
Levodopa	3.25
Metronidazole	12.3
Ascorbic Acid (Vitamin C)	16.95
Acetaminophen	15.6
Biotin	5
Cyclosporine	0.6
Rifampicin	6.5
Doxycycline	3.2
Theophylline	11.4
Ibuprofen	50
EDTA-2Na	4

The effect of human anti-mouse antibodies (HAMA), rheumatoid factor (RF) and human serum total protein was evaluated using human serum samples. Each potential interferent was added to HCG/β-HCG human serum samples and tested using 3 lots of reagents. For all substances tested, no significant interference was defined as recovery ± 10% of initial value. The potential interferents and the highest concentration tested which did not cause significant interference are listed below.

Potential Interferent	Highest concentration tested at which no significant interference is observed
HAMA	401 ng/mL
RF	1745 IU/mL
Total protein	15 g/dL

f. Hook Effect

Six samples with HCG/β-HCG concentrations from 5000 to 1000000 mIU/mL were prepared by spiking HCG/β-HCG WHO 5th International Standard into HCG/β-HCG free serum samples. Serial dilutions of these samples were made and tested using 3 different lots of the reagent. The obtained results indicated no HOOK effect was observed within HCG/β-HCG concentration of 1000000 mIU/mL.

2. On-board Dilution Recovery

Verification studies were performed to determine the sample recovery after a 1:50 dilution is performed by both manually and automatically. Twelve serum samples with HCG/β-HCG concentrations from 4475 to 223750 mIU/mL as determined by the predicate device were tested using three reagent lots and three instruments with the 1:50 dilution. The percent differences for the diluted specimen versus the expected concentration were within 10%. The dilution study results support the claim that samples with HCG/β-HCG concentrations above 4680 mIU/mL may be diluted at 1:50 to obtain results up to 223750 mIU/mL.

3. Comparison Studies

A method comparison study was performed with 201 human serum samples with concentrations ranging from 1.1 to 4934 mIU/mL as determined by the predicate device. The comparison of the MAGLUMI HCG/β-HCG assay (y) with the predicate device, Beckman Access Total β-HCG assay (x), produced the following linear regression equations:

All three sites	$Y = 0.988X + 1.995$, $R^2 = 0.993$
Site 1	$Y = 0.997X – 1.357$, $R^2 = 0.995$
Site 2	$Y = 0.997X + 7.614$, $R^2 = 0.993$
Site 3	$Y = 0.970X + 0.436$, $R^2 = 0.992$

4. Expected values/Reference range:

A total of 431 serum samples from non-pregnant, apparently healthy females (20 years and older) were tested according to the procedure in CLSI C28-A3. The expected normal range Maglumi HCG/β-HCG is the following.

Category	Number	Median (mIU/mL)	95th Percentile (mIU/mL)
20-39 years old	138	< 1.1	< 1.1
≧40 years old, Pre-menopausal	149	< 1.1	1.6
≧51 years old, Post-menopausal	144	2.4	7.8

12. Conclusion

Based on the test principle and acceptable performance characteristics including precision, interference, specificity and method comparison of the device, it is concluded that the MAGLUMI 2000 HCG/β-HCG is substantially equivalent to the predicate.