DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 14, 2017

SHENZHEN NEW INDUSTRIES BIOMEDICAL ENGINEERING CO.,LTD
c/o JOE SHIA, DIRECTOR
LSI INTERNATIONAL INC.
504E DIAMOND AVE., SUITE F
GAITHERSBURG MD 20877

Re: K162698
Trade/Device Name: MAGLUMI 2000 TSH, MAGLUMI 2000 Immunoassay Analyzer
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: II
Product Code: JLW, JJE
Dated: May 29, 2017
Received: June 5, 2017

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. 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,

Kellie B. Kelm -S

for 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)*
K162698

Device Name
MAGLUMI 2000 TSH

Indications for Use *(Describe)*
The MAGLUMI 2000 TSH assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH) in human serum. The measurement of TSH is used in the diagnosis of thyroid disorders.

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."*

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)*
K162698

Device Name
MAGLUMI 2000 Immunoassay Analyzer

Indications for Use *(Describe)*
The MAGLUMI 2000 Immunoassay system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical serum specimens. The MAGLUMI 2000 Immunoassay system's assay application utilizes chemiluminescents technology for clinical use.

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."*

K162698

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: July 12, 2017

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 TSH

Classification: MAGLUMI 2000 Immunoassay System
Class II (assay); Class I (instrument)

| Product Code | CFR # | Product Abbreviation | Product Name |
|---|---|---|---|
| JLW | 862.1690 | TSH | Thyroid Stimulating Hormone |
| JJE | 862.2160 | | Analyzer, Chemistry (Photometric, Discrete), For Clinical Use |

5. Predicate Devices:
K083844, Siemens ADVIA Centaur TSH3
K151792, Siemens Trinidad Immunoassay (IM) System

6. Intended Use:
The MAGLUMI 2000 Immunoassay system is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical serum specimens. The MAGLUMI 2000 Immunoassay system's assay application utilizes chemiluminescents technology for clinical use.

The MAGLUMI 2000 TSH assay is for in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH) in human serum. The measurement of TSH is used in the diagnosis of thyroid disorders.

7. Device Description:

**MAGLUMI 2000 System:**

The MAGLUMI 2000 system is a floor model, fully automated instrument system that utilizes chemiluminescent technology and uses pre-packaged reagent packs to measure a variety of analytes in human body fluids. It is controlled through a combination of custom and off-the-shelf software.

**MAGLUMI 2000 TSH assay:**

MAGLUMI 2000 TSH kit consists of the following reagents:

Magnetic Microbeads- coated with anti-TSH monoclonal antibody, phosphate buffer, NaN3(<0.1%) and ProClin® 300

Calibrator Low-TSH antigen (human origin), phosphate buffer, bovine serum, NaN3(<0.1%) and ProClin® 300

Calibrator High- TSH antigen (human origin), phosphate buffer, bovine serum, NaN3(<0.1%) and ProClin® 300

Buffer- tris buffer, HAMA Blocker, BSA, NaN3(<0.1%) and ProClin® 300

ABEI Label- labeled with anti-TSH monoclonal antibody (mouse), tris buffer, containing BSA, NaN3(<0.1%) and ProClin® 300

Control 1- TSH antigen (human origin), phosphate buffer, bovine serum NaN3(<0.1%) and ProClin® 300

Control 2- TSH antigen (human origin), phosphate buffer, bovine serum NaN3(<0.1%) and ProClin® 300

Control 3- TSH antigen (human origin), phosphate buffer, bovine serum NaN3(<0.1%) and ProClin® 300.

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

**Instrument Similarities and Differences**

| Item | Predicate Device | Subject Device |
|---|---|---|
| Intended Use/ Indication for Use | Automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens | Same |
| Principles of Assay Operation | Chemiluminescence using magnetic-particle solid phase and chemiluminescent label | Same |
| Type of System | Random Access and Batch | Random Access,Batch,STAT |
| Throughput Rate | 120 to 240 tests/hr | Up to 180 tests/hr |
| Optical System | PMT used in photon counting mode | Same |
| Test Processing | Sample scheduling optimized for throughput; continuous operation | Same |
| Sample Container | Sample cups or primary tubes may be used | Same |
| Dispense System | Automated pipetting of samples using precision syringe | Same |
| Sample Type | Serum, plasma, urine, whole blood hemolysate, amniotic | Serum only |
| Sample Volume | 10 to 200 µl | 5 to 200 µl |
| Calibration | 2 point user run calibration | Same |
| Controls | Capability to dilute controls | Same |

## Assay Similarities and Differences

| Item | Predicate Device | Subject Device |
|---|---|---|
| Intended Use/ Indication for Use | For in vitro diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in serum and plasma using the ADVIA Centaur XP system.<br>A thyroid stimulating hormone test system is a device intended to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. | For in vitro chemiluminescent immunoassay in the quantitative determination of thyroid-stimulating hormone (TSH) in human serum using the MAGLUMI 2000 fully- auto chemiluminescence immunoassay system. The measurement of TSH is used in the diagnosis of thyroid disorders. The Maglumi 2000 system is intended for prescription use. |
| Specimen | Serum , heparinized plasma, EDTA plasma | serum |
| Measured Analyte | Thyroid-stimulating hormone | same |
| Measurement | Quantitative | same |
| Test principle | Sandwich chemiluminescent immunoassay | same |
| Detection Antibody | Monoclonal murine anti-TSH antibody BSA conjugate labeled with acridinium ester (AE) | anti-TSH monoclonal antibody labeled with ABEI |
| Capture Antibody | Anti-fluorescein labeled (FITC) monoclonal murine anti-TSH antibody covalently bound to paramagnetic particles (PMP) | anti-TSH monoclonal antibody bound to magnetic microbeads |
| Measuring range | 0.008 µIU/ml – 150 µIU/ml | 0.02µIU/ml-91.78 µIU/ml (0.02mIU/L-91.78mIU/L) |
| Sample size | 100 µL | same |
| Calibration | 2 Point | same |
| Calibrator | Lyophilized TSH-Ultra low and high Calibrators, 2 levels | Low and high Calibrators, 2 levels, ready for use |
| Calibrators packaging | Provided with reagent kit | same |
| Automated | Yes | same |

10. Test Principle

The MAGLUMI TSH assay is a sandwich chemiluminescence immunoassay. The sample (or calibrator/control, if applicable), magnetic particles coated with anti-TSH monoclonal antibody, buffer and ABEI labeled with another monoclonal antibody are mixed thoroughly and incubated at 37°C, forming sandwich of immuno-complexes. After precipitation in a magnetic field, the supernatant is decanted and then a wash cycle is performed. Subsequently, the starters 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 indicative of TSH concentration present in samples, calibrators or controls.

11. Performance Characteristics

1. Analytical Performance

a. Precision

The precision was determined using the CLSI EP5-A2 protocol as a guide. The study was conducted on three different instruments with four controls, two calibrators, six spiked patient serum pools and four native patient sample 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 obtained are summarized in the following tables:

| Sample | Mean (N=240) | Within-Run | | Between-Run | | Between-Day | | Total | |
|---|---|---|---|---|---|---|---|---|---|
| | | SD | %CV | SD | %CV | SD | %CV | SD | %CV |
| Control 1 | 0.221 | 0.010 | 4.73% | 0.005 | 2.40% | 0.0059 | 2.696% | 0.013 | 5.95% |
| Control 2 | 0.620 | 0.027 | 1.38% | 0.013 | 2.04% | 0.011 | 1.718% | 0.032 | 5.12% |
| Control 3 | 6.546 | 0.277 | 4.23% | 0.233 | 3.57% | 0.066 | 1.008% | 0.368 | 5.62% |
| Control 4 | 17.961 | 0.711 | 3.96% | 0.354 | 1.97% | 0.2836 | 1.579% | 0.843 | 4.70% |
| Calibrator low | 0.330 | 0.015 | 4.50% | 0.014 | 4.38% | 0 | 0% | 0.019 | 5.86% |
| Calibrator high | 38.037 | 1.372 | 3.61% | 0.363 | 0.96% | 0.411 | 1.080% | 1.478 | 3.89% |
| Serum Pool 1 | 1.257 | 0.05 | 3.95% | 0.035 | 2.82% | 0.029 | 2.296% | 0.067 | 5.37% |
| Serum Poo2 | 6.401 | 0.102 | 1.60% | 0.164 | 2.56% | 0 | 0% | 0.157 | 2.447% |
| Serum Pool 3 | 11.880 | 0.472 | 3.97% | 0.42 | 3.56% | 0.177 | 1.490% | 0.66 | 5.54% |
| Serum Pool 4 | 38.67 | 1.221 | 3.24% | 0.788 | 2.09% | 0.489 | 1.30% | 1.533 | 4.07% |
| Serum Pool 5 | 64.309 | 2.371 | 3.69% | 2.022 | 3.14% | 0 | 0% | 3.109 | 4.83% |
| Native patient sample pool 1 | 0.577 | 0.025 | 4.33% | 0.012 | 2.08% | 0.01 | 1.73% | 0.029 | 5.02% |
| Native patient sample pool 2 | 1.137 | 0.048 | 4.222% | 0.032 | 2.81% | 0.033 | 2.90% | 0.067 | 5.89% |
| Native patient sample pool 3 | 5.026 | 0.201 | 3.992% | 0.098 | 1.95% | 0.105 | 2.079% | 0.247 | 4.907% |
| Native patient sample pool 4 | 9.750 | 0.429 | 4.401% | 0.139 | 1.42% | 0.094 | 0.960% | 0.460 | 4.723% |

b. Linearity

The linearity of the MAGLUMI TSH method was determined following the CLSI EP6-A procedure.Two samples were identified having TSH concentrations covering the reportable range. A series of intermediate serum samples were prepared by diluting the high level sample (105 μIU/mL) with the low level sample (0 μIU/mL). The obtained results are shown in the following tables.

| Sample | Observed (μIU/mL) | Expected (μIU/mL) |
|---|---|---|
| L | 0 | 0 |
| 0.99524L | 0.4896 | 0.5 |
| 0.9524L | 4.983 | 5 |
| 0.9L | 10.691 | 10.5 |
| 0.8L | 21.652 | 21 |
| 0.7L | 30.785 | 31.5 |
| 0.6L | 42.555 | 42 |
| 0.5L | 52.278 | 52.5 |
| 0.4L | 62.105 | 63 |
| 0.3L | 75.052 | 73.5 |
| 0.2L | 83.218 | 84 |
| 0.1L | 94.807 | 94.5 |
| H | - | 105 |

The assay are linear between 0.02 and 91.78μIU/mL with the following relationship:

Observed = 1.0001 (Expected) + 0.0474, $R^2$ = 0.9990

c. Stability and Traceability

The standardization of the MAGLUMI TSH method is traceable to the WHO international standard for human TSH (IRP 81/565).

All TSH controls are traceable to the WHO international standard for human TSH (IRP 81/565). All TSH calibrators are traceable to the WHO international standard for human TSH (IRP 81/565). 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. Shelf life stability experiments showed that the reagent is stable for 12 months at 2-8ºC.

Open kit is stable for four weeks at 2-8ºC.

d. Detection Limit

Detection limit studies were performed following CLSI EP17-A guidelines. The following values for the test have been verified.

| | |
|---|---|
| LOB | 0.001 µIU/ml |
| LOD | 0.006 µIU/ml |
| LOQ | 0.01 µIU/ml |

Hook effect: The test was not found susceptible to hook effect as it would display signal increases with increasing TSH concentration. No hook effect was observed at TSH concentrations up to 3000 µIU/mL

e. Interference

Clinical serum samples may contain substances that could potentially interfere with the test. The following compounds were added to human serum samples with a low TSH concentration and a high TSH concentration. None of the serum samples showed any deviation from the expected results. No interference was observed for these compounds at the levels indicated below.

| Interference | Human Serum TSH Concentrations (µIU/mL) | Interference Substance |
|---|---|---|
| Conjugate Bilirubin | 0.97 and 5.4 | 60 mg/dL |
| Hemoglobin | 0.97 and 5.4 | 2000 mg/dL |
| Triglycerides | 0.97 and 5.4 | 1000 mg/dL |
| Acetaminophen | 0.7 and 6.1 | 20 mg/dl |
| Ibuprofen | 0.7 and 6.1 | 50 mg/dl |
| Aspirin | 0.7 and 6.1 | 50 mg/dl |
| Biotin | 0.7 and 6.1 | 10 ng/ml |
| Unconjugate bilirubin | 0.7 and 6.1 | 40 mg/dl |
| Rheumatoid factor | 0.7 and 6.1 | 124 IU/ml |
| human anti-mouse antibodies (HAMA) | 0.13 and 4.71 | 300ng/mL |
| Total protein | 0.7 and 6.1 | 12.5 mg/ml |

f. Specificity

Human serum samples with various TSH concentrations were spiked with potential cross reactants FSH, LH, and hCG dissolved in PBS with 1% BSA and tested in MAGLUMI TSH system. Controls were prepared by spiking samples with equal volumes of the PBS-BSA solution used in dissolving the FSH, LH, and hCG. The concentrations of spiked and control samples were recorded, and the cross reactivity were calculated. Less than 2% cross-reactivity was found for hCG, FSH, and LH at 200 IU/ml, 1500 mIU/mL and 600 mIU/mL respectively.

2. Comparison Studies

   Patient serum samples (n=337) with TSH values ranging from 0.02 – 91.78 μIU/mL were collected and evaluated. Linear regression was used to correlate the MAGLUMI TSH assay to the ADVIACENTAUR TSH assay.The results yielded the following linear regression equation:

   $Y = 1.0178X - 0.0773$, $R^2 = 0.9974$

3. Expected values/Reference range:

   A total of 126 serum samples from normal, apparently healthy adult (22 years and older) individuals were tested according to the procedure in CLSI C28-A3. The expected normal range is 0.658 – 4.864 μIU/mL based on the central 95% of the frequency distribution.

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 TSH is substantially equivalent to the predicate.