April 12, 2024

Shenzhen New Industries Biomedical Engineering Co., Ltd
% Joe Shia
Director
LSI International Inc
504 East Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K232587
Trade/Device Name: MAGLUMI 25-OH Vitamin D, MAGLUMI X3 Fully auto chemiluminescence immunoassay analyzer
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D Test System
Regulatory Class: Class II
Product Code: MRG, JJE
Dated: February 25, 2024
Received: February 26, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232587

Device Name
MAGLUMI 25-OH Vitamin D
MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer

Indications for Use *(Describe)*
The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens.

The MAGLUMI 25-OH Vitamin D is an in vitro chemiluminescence immunoassay for the quantitative determination of 25-OH Vitamin D (25-OH VD) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer, and the assay is used for an aid in assessment of vitamin D sufficiency.

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.

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510(k) SUMMARY

K232587

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

1. Date: April 11, 2024

2. Submitter: Shenzhen New Industries Biomedical Engineering Co., Ltd.
No.23, Jinxiu East Road, Pingshan District,
518122 Shenzhen, P.R. China

3. Contact person: Joe Shia
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504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email:shiajl@yahoo.com

4. Device Name: MAGLUMI 25-OH Vitamin D
MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer

Classification: Class II (assay) and Class I (instrument)

Product Code	CFR #	Product Name
MRG	862.1825	Vitamin D Test System
JJE	862.2160	Analyzer, Chemistry (Photometric, Discrete), For Clinical Use

5. Predicate Devices:
K191499, SNIBE MAGLUMI 2000 25-OH Vitamin D
K162698, SNIBE MAGLUMI 2000 Immunoassay Analyzer

6. Device Description:
MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer:
The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer is a fully automated instrument system designed to perform in vitro diagnostic tests on clinical specimens. The system utilizes chemiluminescent technology and uses pre-packaged reagent packs for qualitative or quantitative analysis of the analytes in human samples. The analyzer performs automatic sample pipetting, reagent loading, incubation, washing, measurements, and result calculations.

MAGLUMI 25-OH Vitamin D assay:
MAGLUMI 25-OH Vitamin D kit consists of the following reagents:

Magnetic Microbeads- coated with anti-25-OH VD antibody in PBS buffer, NaN3 (<0.1%).
Calibrator Low- A low concentration of 25-OH VD antigen in Carbonate buffer, NaN3 (<0.1%).
Calibrator High- A high concentration of 25-OH VD antigen in Carbonate buffer, NaN3 (<0.1%).
Buffer- Acidic buffer
ABEI Label- ABEI labeled with anti-25-OH VD antibody (~0.500 μg/mL) in PBS buffer, NaN3 (<0.1%).
Control 1- A low concentration of 25-OH VD antigen in Carbonate buffer, NaN3 (<0.1%).
Control 2- A high concentration of 25-OH VD antigen in Carbonate buffer, NaN3 (<0.1%).

7. Intended Use:
   The MAGLUMI X3 Fully-auto chemiluminescence immunoassay analyzer is an automated, immunoassay analyzer designed to perform in vitro diagnostic tests on clinical specimens.

   The MAGLUMI 25-OH Vitamin D is an in vitro chemiluminescence immunoassay for the quantitative determination of 25-OH Vitamin D (25-OH VD) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer, and the assay is used for an aid in assessment of vitamin D sufficiency.

8. Standard/Guidance Documents
   Clinical and Laboratory Standards Institute EP5-A3 – Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline-Third Edition.
   Clinical and Laboratory Standards Institute EP6-A – Evaluation of the Linearity of Quantitative Measurement Procedures: A statistical approach; Approved guideline
   Clinical and Laboratory Standards Institute EP17-A2: Evaluation of detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition
   Clinical and Laboratory Standards Institute EP7-A2 – Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition
   Clinical and Laboratory Standards Institute EP9-A3 – Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Third Edition.

9. Substantial Equivalence Information

Instrument Similarities and Differences

Item	Predicate Device	Candidate 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, Batch, STAT	Same
Throughput Rate	Up to 180 tests/hr	Up to 200 tests/hr
Optical System	PMT used in photon counting mode	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	Serum and Plasma
Sample Volume	5 to 200 µl	10 to 200 µl
Reagent Volume	10 to 200 µl	10 to 450 µl

Assay Similarities and Differences

Item	Predicate Device	Candidate Device
Intended Use/ Indication for Use	For the quantitative determination of 25-hydroxyvitamin D. The measurement of 25-OH Vitamin D is to be used in the assessment of vitamin D sufficiency.	Same
Specimen	Serum	Serum and K2 EDTA Plasma
Measurement	Quantitative	Same
Calibration	2 point	Same
Calibrator	Calibrator Low and Calibrator High	Same
Automated	Yes	Same
Capture antibody	Magnetic microbeads coated with 25-OH Vitamin D monoclonal antibody	Same
Test principle	Two-step Competitive chemiluminescence immunoassay (CLIA)	Sandwich chemiluminescence immunoassay (CLIA)
Measuring range	5.371-143 ng/ml	5.371-150 ng/ml
Detection	ABEI-labeled 25-OH Vitamin D antigen	ABEI-labeled 25-OH Vitamin D antibody
Sample size	100 µL	10 µL

Traceability	NIST RMP 2972	NIST SRM 2972a

10. Test Principle

The 25-OH Vitamin D assay is a sandwich chemiluminescence immunoassay for the quantitative determination of total 25-OH vitamin D in human serum and plasma.

The sample, magnetic microbeads coated with anti-25-OH VD antibody and buffer are mixed thoroughly, incubating and performing a wash cycle after a precipitation in a magnetic field. ABEI labeled with another anti-25-OH VD antibody are then added, reacting to form sandwich complexes and incubating. 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 as relative light units (RLUs), which is proportional to the concentration of 25-OH VD present in the sample.

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 two controls, two calibrators, one spiked patient serum pool and three 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 (in ng/mL) obtained are summarized in the following table:

Sample	N	Mean (ng/mL)	Repeatability		Between-Run		Between-Day		Total (within instrument)		Reproducibility (across instruments)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Calibrator Low	240	6.986	0.270	3.86	0.214	3.06	0.398	5.70	0.526	7.53	0.564	8.07
Calibrator High	240	97.698	1.543	1.58	1.976	2.02	0.923	0.94	2.672	2.73	2.692	2.76
Control 1	240	19.962	0.512	2.56	0.706	3.54	0.956	4.79	1.294	6.48	1.306	6.54
Control 2	240	50.181	1.405	2.80	1.150	2.29	1.398	2.79	2.292	4.57	2.292	4.57
Spiked serum pool	240	130.310	0.770	0.59	2.024	1.55	0.508	0.39	2.224	1.71	2.305	1.77
Native Serum Pool 1	240	30.084	1.027	3.41	0.626	2.08	1.294	4.30	1.766	5.87	1.766	5.87
Native Serum Pool 2	240	8.376	0.469	5.60	0.251	3.00	0.299	3.57	0.610	7.28	0.610	7.28
Native Serum Pool 3	240	100.082	1.022	1.02	2.128	2.13	0.517	0.52	2.417	2.42	2.417	2.41

b. Linearity

The linearity of the MAGLUMI 25-OH Vitamin D method was determined following the CLSI EP6-A procedure. Eleven levels of linearity samples were prepared by blending a low serum sample pool and a high serum sample pool to span the whole measuring range with 25-OH Vitamin D concentrations from 1.8 to 195.0 ng/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 1.8 and 195.0 ng/mL with the following relationship:
Observed = 1.0016 (Expected) - 0.4938, $R^2 = 0.9974$

c. Stability
Real time stability study showed that both controls and reagent kits are stable for 18 months at 2-8ºC.

d. Detection Limit

Detection limit studies were performed following CLSI EP17-A2 guidelines.
The limit of blank (LOB) is the 95th percentile value from 60 measurements of 25-OH Vitamin D depleted serum samples using 3 different lots of 25-OH Vitamin D reagents over 3 days. The LOB corresponds to the concentration below which analyte-free samples are found with a probability of 95% and was determined to be 0.95 ng/mL.
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 60 replicates over 3 days per sample using 3 lots of reagents. LOD was determined to be 1.4 ng/mL.
The limit of quantitation (LOQ) was determined by measuring six low serum samples, in five replicates per run, one run per day, over 3 days, using 3 lots of reagents. LOQ is defined as the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20% and was determined to be 2.289 ng/mL.

e. Interference
A cross reactivity study was performed using three base serum samples containing total 25-OH VD 10 ng/mL, 50 ng/mL and 100 ng/mL respectively. These samples were spiked with various cross reactants and measured for these solutions using 3 lots of reagents. The following table shows cross reactivity of potential cross reactant.

Cross Reactant	%Cross-reactivity
25-OH Vitamin D2	100.41%
25-OH Vitamin D3	98.17%
Vitamin D2	-0.33%
Vitamin D3	0.18%
1,25-(OH)2-Vitamin D3	0.19%
1,25-(OH)2-Vitamin D2	0.03%
3-epi-25OH D3	0.46%

The effect of endogenous substances were evaluated using human serum pools. For each substance, three serum samples containing 10, 50 and 100 ng/mL concentration of 25-OH Vitamin D 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	250
triglyceride	500
Uric acid	20
Cholesterol	300

The effect of common drugs and interference substances were evaluated using human serum pools. For each substance, three serum samples containing 10, 50 and 100ng/mL concentration of 25-OH Vitamin D were analyzed. 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	340
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

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 25-OH Vitamin D 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	6.25 g/dL

2. Comparison Studies

   A method comparison study was performed with 329 human serum samples with concentrations ranging from 5.933 to 142.1 ng/mL. In the study, 329 native, single donor patient (121 male, 208 female, age 7 to 98 years) serum samples were tested on the candidate devices and the comparator method. The comparison of the MAGLUMI 25-OH Vitamin D assay (y) with the predicate device, MAGLUMI 2000 25-OH Vitamin D assay (x), produced the following

   Passing-Bablok: y=0.989x+0.249, R=0.997

3. Expected values/Reference range:

   A total of 312 serum samples from normal, apparently healthy adult (21 years and older) individuals were tested according to the procedure in CLSI EP28-A3c. The expected normal range is 7.4 – 45.1 ng/mL based on the central 95% of the frequency distribution.
   The 312 samples were collected from three regions (Central, Southeast and Northeast) in the US, including 181 males and 131 females. The whole samples met following season distribution:

Season	Spring	Summer	Autumn	Winter
Samples size	109	78	28	97
Percentage	35%	25%	9%	31%

4. Matrix Comparison:
   A matrix comparison study was conducted by comparing values obtained from samples drawn into serum and plasma collection tubes. The result of the serum sample was compared with the result of each plasma sample from the same donor. Total 78 serum/plasma pairs were tested. The results show the following:

   Passing-Bablok: y=0.977x-0.0256, R^2=0.9938

5. Clinical Studies:
   Not applicable.

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 25-OH Vitamin D is substantially equivalent to the predicate.