December 19, 2025

Diazyme Laboratories, Inc.
Abhijit Datta
VP Operations
12889 Gregg Ct
Poway, California 92130

Re: K253358
Trade/Device Name: Diazyme Human Kappa (κ) Free Light Chain Assay
Diazyme Human Lambda (λ) Free Light Chain Assay
Regulation Number: 21 CFR 866.5550
Regulation Name: Immunoglobulin (Light Chain Specific) Immunological Test System
Regulatory Class: Class II
Product Code: DFH, DEH
Dated: September 30, 2025
Received: September 30, 2025

Dear Abhijit Datta:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Ying Mao -S

Ying Mao, Ph.D.
Branch Chief
Division of Immunology and Hematology 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)*
K253358

Device Name
Diazyme Human Kappa (κ) Free Light Chain Assay
Diazyme Human Lambda (λ) Free Light Chain Assay

Indications for Use *(Describe)*
The Diazyme Human Kappa (κ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Kappa Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Kappa FLC in conjunction with Lambda FLC aids in the diagnosis and monitoring of multiple myeloma and aids in the evaluation of monoclonal gammopathy of undetermined significance (MGUS) in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.

The Diazyme Human Lambda (λ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Lambda Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Lambda FLC in conjunction with Kappa FLC aids in the diagnosis and monitoring of multiple myeloma and aids in the evaluation of monoclonal gammopathy of undetermined significance (MGUS) in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.

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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I. Background Information:

A. 510(k) Number

K253358

B. Applicant

Diazyme Laboratories Inc.

C. Proprietary and Established Names

Diazyme Human Kappa (κ) Free Light Chain Assay
Diazyme Human Lambda (λ) Free Light Chain Assay

D. Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DFH, DEH	Class II	21 CFR 866.5550 - Immunoglobulin (Light Chain Specific) Immunological Test System	IM - Immunology

II. Submission/Device Overview:

A. Purpose for Submission:

Modification of a previously cleared device: Addition of intended use as an aid in the evaluation of Monoclonal Gammopathy of Undetermined Significance (MGUS) on validated analyzers

B. Measurand:

Kappa (κ) Free Light Chain (FLC)
Lambda (λ) Free Light Chain (FLC)

C. Type of Test:

Latex particle enhanced immunoturbidimetric, quantitative

III. Intended Use/Indications for Use:

A. Intended Use(s):

See Indications for Use below.

B. Indication(s) for Use:

The Diazyme Human Kappa (κ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Kappa Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Kappa FLC in conjunction with Lambda FLC aids in the diagnosis and monitoring of multiple myeloma and aids in the evaluation of monoclonal gammopathy of undetermined significance (MGUS), in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.

The Diazyme Human Lambda (λ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Lambda Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Lambda FLC in conjunction with Kappa FLC aids in the diagnosis and monitoring of multiple myeloma and aids in the evaluation of monoclonal gammopathy of undetermined significance (MGUS), in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.

C. Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Diazyme Human Kappa (κ) Free Light Chain Assay
Warning: Kappa FLC result for a given specimen determined with assays and/or instrument platforms from different manufacturers can vary due to differences in assay methods and reagent Negative Rate. The results reported by the laboratory to the physician must include the identity of the FLC assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of serially monitoring a patient, the assay method used for determining the Kappa FLC levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory should confirm baseline values for patients being serially monitored.

Evaluation of monoclonal gammopathy of undetermined significance (MGUS):

- The performance has not been sufficiently studied in Light Chain MGUS patients.
- Patients with renal disease or inflammation may have elevated levels of kappa and lambda free light chains (FLC).
- The performance has not been fully evaluated in all races/ethnicities in the intended use population.

Diazyme Human Lambda (λ) Free Light Chain Assay
Warning: Lambda FLC results for a given specimen determined with assays and/or instrument platforms from different manufacturers can vary due to differences in assay methods and reagent

Negative Rate. The results reported by the laboratory to the physician must include the identity of the FLC assay used. Values obtained with different assay methods cannot be used interchangeably. If, in the course of serially monitoring a patient, the assay method used for determining the Lambda FLC levels is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory should confirm baseline values for patients being serially monitored.

Evaluation of monoclonal gammopathy of undetermined significance (MGUS):

- The performance has not been sufficiently studied in Light Chain MGUS patients.
- Patients with renal disease or inflammation may have elevated levels of kappa and lambda free light chains (FLC).

The performance has not been fully evaluated in all races/ethnicities in the intended use population.

D. Special Instrument Requirements:

Roche cobas c501 analyzer and validated analyzers

IV. Device/System Characteristics:

A. Device Description:

No modification is made to the kit components for the Diazyme Human Kappa (κ) and Lambda (λ) Free Light Chain Assays cleared in k153394.

The Diazyme Human Kappa (κ) Free Light Chain Assay is comprised of the following reagents:

Reagent R1: Tris buffer solution
Reagent R2: Carboxyl Polystyrene particles coated with polyclonal rabbit and goat anti-Kappa FLC antibodies Calibrators: A five-level set in liquid form (5 x 1 mL)

Material required but not provided
Controls Set: Two levels, serum based, liquid form

The Diazyme Human Lambda (λ) Free Light Chain Assay is comprised of the following reagents:

Reagent R1: Tris buffer solution
Reagent R2: Carboxyl Polystyrene particles coated with polyclonal rabbit anti-Lambda FLC antibodies.
Calibrators: A five-level set in liquid form (5 x 1 mL)

Material required but not provided
Controls Set: Two levels, serum based, liquid form

B. Principle of Operation:

The Diazyme Human Kappa (κ) Free Light Chain Assay or the Diazyme Human Lambda (λ) Free Light Chain Assay is based on a latex enhanced immunoturbidimetric assay. Kappa FLC or Lambda FLC in the sample binds to specific anti-Kappa FLC or anti-Lambda FLC antibody, which is coated on latex particles, and causes agglutination. The degree of the turbidity caused by agglutination can be measured optically and is proportional to the amount of Kappa FLC or Lambda FLC in the sample. The instrument calculates the Kappa FLC or Lambda FLC concentration by interpolation of obtained signal of a 6-point calibration curve prepared from calibrators of known concentrations

V. Substantial Equivalence Information:

A. Predicate Device Name(s):

Diazyme Human Kappa (κ) Free Light Chain Assay
Diazyme Human Lambda (λ) Free Light Chain Assay

B. Predicate 510(k) Number(s):

K211648

C. Comparison with Predicate(s):

Device & Predicate Device(s):	K253358 (Subject Device)	K211648 (Predicate)
Device Trade Name	Diazyme Human Kappa Free Light Chain Assay Diazyme Human Lambda Free Light Chain Assay	Same
General Device Characteristic Similarities		
Analyte	Kappa FLC Lambda FLC	Same
Assay Type	Quantitative	Same
Test Method	Turbidimetry	Same
Specimen Type	Serum	Same
Traceability	Internal Reference preparation	Same
Units	mg/L	Same
Detection Antibody	Polyclonal anti-Human Kappa/ antihuman Lambda Free light chain Ig fraction coated on polystyrene latex microparticles.	Same

Reference Interval	Kappa: 2.37 – 20.73 mg/L Lambda: 4.23 – 27.69 mg/L K/L Ratio: 0.22 – 1.74	Same
Analytical Measuring Interval (Kappa)	2.9–150 mg/L 58–3,000 mg/L (extended)	Same
Analytical Measuring Interval (Lambda)	3.5–200 mg/L 70–4,000 mg/L (extended)	Same
Reference Interval	Kappa: 2.4–20.7 mg/L Lambda: 4.2–27.7 mg/L Ratio: 0.22–1.74 mg/L	same
General Device Characteristic Differences		
Intended Use / Indications for Use	The Diazyme Human Kappa (κ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Kappa Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Kappa FLC in conjunction with Lambda FLC aids in the diagnosis and monitoring of multiple myeloma and aids in the evaluation of monoclonal gammopathy of undetermined significance (MGUS) in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.	The Diazyme Human Kappa (κ) Free Light Chain Assay is intended as a latex particle enhanced immunoturbidimetric assay for the quantitative determination of Kappa Free Light Chain (FLC) concentration in serum on validated analyzers. The measurement of Kappa FLC in conjunction with Lambda FLC aids in the diagnosis and monitoring of multiple myeloma in conjunction with other laboratory and clinical findings. For in-vitro diagnostic use only.
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	laboratory and clinical findings. For in-vitro diagnostic use only.	
MGUS Diagnosis Positive Rate and Negative Rate	53.7% Positive Rate 94.0% Negative Rate N = 270 true MGUS N = 266 no MGUS	No claim
MGUS Monitoring Positive Rate and Negative Rate	100% Positive Rate 90.5% Negative Rate N = 84 true stable MGUS N = 2 progressive MGUS	No claim

VI. Standards/Guidance Documents Referenced:

Not applicable

VII. Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Precision/Reproducibility:

   Refer to K153394

2. Linearity:

   Refer to K211648

3. Analytical Negative Rate/Interference:

   Refer to K153394

4. Assay Reportable Range:

   See K153394, K211648

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Refer to K153394

6. Detection Limit:

Refer to K211648

7. Assay Cut-Off:

Refer to K153394 and K184338

B. Comparison Studies:

1. Method Comparison with Predicate Device:

Refer to K153394

2. Matrix Comparison:

N/A

C. Clinical Studies:

MGUS is a clinically asymptomatic premalignant clonal plasma cell or lymphoplasmacytic proliferative disorder. The performance of the Diazyme Human Kappa and Lambda Free Light Chain kits as an aid in the evaluation of MGUS was investigated from the following retrospective clinical studies:

Study 1:

A retrospective study was performed by testing a total of 270 serum samples from clinically confirmed MGUS patients (with IFE positivity) and a total of 266 samples from clinically defined non-MGUS patients with polyclonal immunostimulation (confirmed with negative SPEP/SIFE). Three hospitals were employed for the sample collection, San Francisco General Hospital, (SFGH), University of California at San Francisco Medical Center (UCSF) and Augusta University (AU) for MGUS and non-MGUS samples. Clinical diagnostic criteria and classification for MGUS and related plasma-cell disorders were, as practiced clinically, fulfilled, but were not limited to the criteria outlined by the 'International Myeloma Working Group (IMWG)' consensus. The result of the device was compared to the clinical diagnosis for each sample.

The cohort of 270 MGUS samples included 205 non-IgM MGUS, 40 IgM MGUS and 25 light chain (LC) MGUS. All samples were tested for FLC kappa and lambda levels with the Diazyme Human Kappa and Lambda FLC kits on the cobas c 501 analyzer. FLC κ/λ ratios were also calculated for each sample. The test results for MGUS positive or negative were based on the following criteria:

- For Non-LC MGUS, the test was considered as "MGUS Positive" or "Abnormal" when abnormal FLC κ/λ ratio (outside reference interval, < 0.22 or > 1.74) with IFE positivity was determined.

- For LC MGUS, the test was considered as "MGUS Positive" when abnormal FLC κ/λ ratio (outside reference interval, < 0.22 or > 1.74) with elevated FLC kappa (>20.7 mg/L) or elevated FLC lambda FLC (> 27.7 mg/L) was determined.

One hundred forty-five (145) out of 270 MGUS cases were tested positive by the Diazyme Kappa and Lambda FLC assay with a positive rate of 53.7% (95% CI: 47.6% – 59.8%). The distribution of the cohort and the positivity rate for each clinical type of MGUS are summarized in table 1:

Table 1

MGUS Type	N	n (n/N%) Diazyme positive
Non-IgM MGUS (all)	**205**	**92 (44.9%)**
IgG K	85	48 (56.5%)
IgG L	80	26 (32.5%)
IgA K	25	13 (52.0%)
IgA L	15	5 (33.3%)
IgM MGUS (all)	**40**	**28 (70.0%)**
IgM K	30	24 (80.0%)
IgM L	10	4 (40.0%)
LC-MGUS (all)	**25**	**25 (100%)**
LC-K	15	15 (100%)
LC-L	10	10 (100%)
TOTAL	**270**	**145 (53.7%)**

The 266 samples from patients with confirmed non-MGUS (negative SPE/IFE) polyclonal stimulation (polyclonal hypergammaglobulinemia) were comprised of: connective tissue disease (59); renal disease (46); infection (40); CVD (21); neurological diseases (20); dermatological disease (15); cancers (14); autoimmune diseases (13); B Lymphoma (8); anemia (6); liver disease (5); diabetes (4) and other miscellaneous diseases/conditions (polyarteritis nodosa, vascular disease, gout, immunodeficiency, venous insufficiency, thrombocytosis, leukocytosis, thrombotic microangiopathy, lymphadenopathy, COPD, pulmonary fibrosis, interstitial lung disease, lung nodules) (15). Among 266 non-MGUS samples, 250 of these were determined as negative by the Diazyme Kappa and Lambda FLC assay, indicating a negative agreement of 94.0% (95% CI: 90.4%–96.5%) in this sample cohort. The 16 false positive samples were from patients with the following disorders: cancers (4); renal diseases (3); connective (2); anemia (2); infection/inflammation (2); autoimmune diseases (1); B lymphoma (1); and other diseases/conditions (1).

Study 2:

Another retrospective study was performed by testing 348 serum samples from 84 subjects with clinically stable MGUS and 2 subjects with progressive clinical status converting from MGUS to multiple myeloma (MM). Among 84 MGUS stable subjects, 69 patients were diagnosed with non-IgM MGUS (29 IgG K, 22 IgG L, 11 IgA K, and 7 IgA L), and 11 patients with IgM MGUS (8 IgM K and 3 IgM L), and 4 patients with LC MGUS (1 LC-K, 3 LC-L). The two progressive subjects were one IgG Lambda and one LC-L.

At least three and up to five serial draws were collected from each patient and tested with the Diazyme Human Kappa and Lambda FLC kits on the cobas c 501 analyzer. FLC κ/λ ratio was calculated for each blood draw sample. Since the MGUS has been identified as a precursor to malignant diseases (multiple myeloma or amyloidosis), but not as a disease which requires treatment, no defined criteria in how to interpret consecutive FLC results are available. Therefore, for device evaluation purposes only, the criteria for stable MGUS and progressive MGUS based on test results in this study are defined as follows:

- FLC stable: Stable MGUS defined as < 25% increase in the concentration of the involved FLC in two consecutive assessments. This analysis included MGUS patients with and without abnormal FLC κ/λ ratio of 0.22-1.74

- FLC progressive: Progressive MGUS defined as the FLC κ/λ ratio outside of the reference interval of 0.22 –1.74, and an increase of ≥ 25% in the concentration of the involved light chain at or preceding the diagnosis of MM, for two consecutive assessments.

Seventy six (76) out of 84 clinically stable MGUS subjects were determined as stable by the test and two out of two clinically progressive subjects were determined as progressive by these tests. The summary of the disease type and counts are in table 3 below:

Table 3

Non-Progressive MGUS Type	**N (Subject)**	**Progressive MGUS Type**	**N (Subject)**
Non-IgM MGUS (all)	**69**	**Non-IgM MGUS (all)**	**1**
IgG K	29	IgG K	0
IgG L	22	IgG L	1
IgA K	11	IgA K	0
IgA L	7	IgA L	0
IgM MGUS (all)	**11**	**IgM MGUS (all)**	**0**
IgM K	8	IgM K	0
IgM L	3	IgM L	0
LC-MGUS (all)	**4**	**LC-MGUS (all)**	**1**
LC-K	1	LC-K	0
LC-L	3	LC-L	1
Total	**84**	**Total**	**2**
TOTAL: 86 subjects			

Limitations

- The performance has not been fully evaluated on all race/ethnicity in the intended use population.
- The study included time points of blood draws not indicative of clinical practice. The algorithm using only FLC has not been validated for progression of disease. Furthermore, a small sample size (2 patients) with the subtypes Lambda IgG and LC-L was used to study progression in Study 2. Risk mitigation strategies include that this test is not a stand-alone test for the evaluation of patients with MGUS and the test is to be utilized in conjunction with serum protein electrophoresis and immunofixation blood tests.

D. Clinical Cut-Off:

Refer to K153394 and K220001

E. Expected Values/Reference Range:

Kappa FLC reference range: 2.4–20.7 mg/L
Lambda FLC reference range: 4.2–27.7 mg/L
Kappa/Lambda Ratio reference Range: 0.22–1.74 mg/L