April 18, 2025

Kamiya Biomedical Company, LLC
Shawn Kaplan
Diagnostics Product Manager
12779 Gateway Dr S
Tukwila, Washington 98168

Re: K242170
Trade/Device Name: K-ASSAY CRP (Ver.2)
Regulation Number: 21 CFR 866.5270
Regulation Name: C-Reactive Protein Immunological Test System
Regulatory Class: Class II
Product Code: DCK
Dated: March 21, 2025
Received: March 21, 2025

Dear Shawn Kaplan:

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)*
K242170

Device Name
K-ASSAY CRP (Ver.2)

Indications for Use *(Describe)*
K-ASSAY CRP (Ver.2) is intended to be used for the quantitative determination of C-reactive protein (CRP) in human serum and plasma (potassium-EDTA or lithium-heparin) by immunoturbidimetric assay. Measurement of CRP aids in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. FOR IN VITRO DIAGNOSTIC 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.

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510(k) Summary

510(k) Number: K242170

1. Submitter

Kamiya Biomedical Company, LLC
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Tukwila, WA 98168 U.S.A.

Contact: Shawn Kaplan
Director, Diagnostics

Email: diagnostics@k-assay.com
PH: 206-575-8068
FAX: 206-575-8094

Date Prepared: April 18, 2025

2. Device

Trade Name: K-*ASSAY*® CRP (Ver.2)
Common Name: C-Reactive Protein, Antigen, Antiserum, And Control
Classification Name: C-reactive protein immunological test system
Regulation Number: 21 CFR 866.5270
Regulatory Class: Class 2
Review Panel: Immunology
Product Code: DCK

3. Predicate Device

Trade Name: K-*ASSAY*® CRP (3)
510(k) Number: K023828

4. Device Description

The K-*ASSAY*® CRP (Ver.2) assay quantifies C-reactive protein based on immunoturbidimetric assay. The reagent uses latex combined with goat polyclonal antibody specific to human CRP.

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By adsorbing CRP in the sample to the surface of the latex particles and reacting it with the anti-CRP antibody, specific aggregation corresponding to the CRP concentration occurs. Since the absorbance of the reaction changes in proportion to the amount of aggregation, the concentration of CRP in the sample is determined based on the calibration curve prepared using a standard of known CRP concentrations.

The K-*ASSAY*® CRP (Ver.2) assay can be run using a chemistry analyzer. 6 levels of calibrators from the K-*ASSAY*® CRP Calibrator (Ver.2) calibrators are used for quantifying the levels of CRP present in the patient's sample.

5. Intended Use / Indications for Use

K-*ASSAY*® CRP (Ver.2) is intended to be used for the quantitative determination of C-reactive protein (CRP) in human serum and plasma (potassium-EDTA or lithium-heparin) by immunoturbidimetric assay. Measurement of CRP aids in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. FOR IN VITRO DIAGNOSTIC USE.

6. Comparison With Predicate Device

The table below describes the similarities and differences between the candidate and predicate devices. Substantial equivalence was demonstrated by direct method comparison testing as well as comparison of various assay performance characteristics.

Item	**K-*ASSAY*® CRP (Ver.2) assay (candidate device)**	**K-*ASSAY*® CRP (3) assay (predicate device)**
Classification	Class 2 (866.5270)	Class 2 (866.5270)
Product Code	DCK	DCK
Indications for Use	K-*ASSAY*® CRP (Ver.2) is intended to be used for the quantitative determination of C-reactive protein (CRP) in human serum and plasma (potassium-EDTA or lithium-heparin) by immunoturbidimetric assay. Measurement of CRP aids in the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases. FOR IN VITRO DIAGNOSTIC USE.	K-*ASSAY*® CRP (3) is intended to be used as a high-sensitive assay for the quantitative determination of CRP in serum and plasma by immunoturbidimetric assay. Measurement of C-Reactive Protein aids in the detection and evaluation of tissue injury, inflammatory disorders, and related diseases.
Assay	Latex-enhanced (immuno)turbidimetric assay	Latex-enhanced (immuno)turbidimetric assay
Calibration:	6 levels (0.0, 10.0, 50.0, 150.0, 300.0 and 400.0 mg/L)	Multi-point calibrators E, D and F; 5 levels for each calibrator set
Range:	5.0 - 400.0 mg/L	0.2 – 480 mg/L

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Precision	Single Site Repeatability CV = 0.4 to 1.8 % Between-Run CV = 0.0 to 1.4 % Within-Day CV = 0.7 to 1.8 % Between-Day CV = 0.0 to 1.7 % Within-Laboratory CV = 0.8 to 2.4 % Multi-Site Repeatability CV = 0.5 to 1.5 % Between-Run CV = 0.0 to 1.1 % Between-Day CV = 0.6 to 1.8 % Between-Site CV = 0.9 to 1.8 % Reproducibility CV = 1.1 to 2.5 %	Within Run CV = 0.53 to 0.81 % Between Runs CV = 0.39 to 1.88%
Interferences	The following substances were tested up to the listed concentrations, and no significant interference was observed: <u>Endogenous Substances</u> Bilirubin C, (Conjugated) 40 mg/dL Bilirubin F (Unconjugated) 40 mg/dL Cholesterol 300 mg/dL Hemoglobin 1,000 mg/dL Intralipid 500 mg/dL Rheumatoid Factor 1,000 IU/mL Triglycerides 1,000 mg/dL <u>Exogenous Substances</u> Acetaminophen 1.5 mM Amoxicillin 400 µmol/L Aspirin (Acetylsalicylic Acid) 3.6 mM Cephalexin 360 µmol/L Fluconazole 480 µmol/L Ibuprofen 2.5 mg/dL Methotrexate 1,400 µmol/L Prednisolone 2 µmol/L Vitamin C (Ascorbic Acid) 500 mg/L	Bilirubin C No interference up to 30 mg/dL Bilirubin F No interference up to 30 mg/dL Hemoglobin No interference up to 500 mg/dL Lipid No interference up to 5% Intrafat Rheumatoid Factor No interference up to 560 IU/mL
Method Comparison	y = K-*ASSAY*® CRP (Ver.2), x = predicate device y = 1.005x - 0.002 r = 0.999 n = 175 clinical native serum samples	

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7. Standards and Guidance Documents

The following standards and guidance documents have been used as a basis for the procedures described in this submission:

CLSI Guidelines:

CLSI EP05-A3: Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. October 2014.

CLSI EP06-Ed2: Evaluation of Linearity of Quantitative Measurement Procedures – Second Edition. November 2020.

CLSI EP07: Interference Testing in Clinical Chemistry – Third Edition. April 2018.

CLSI EP09c: Measurement Procedure Comparison and Bias Estimation Using Patient Samples – Third Edition. June 2018.

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. June 2012.

CLSI EP25-Ed2: Evaluation of Stability of In Vitro Medical Laboratory Test Reagents - Second Edition. April 2023.

CLSI EP28-A3c: Defining, Establishing, and Verifying Reference Intervals in the Clinical
Laboratory; Approved Guideline - Third Edition. October 2010.

FDA Guidance:
Guidance for Industry and FDA Staff : Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays. September 2005.

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8. Performance Data

Testing was performed to confirm assay performance. A summary of results follows.

Method Comparison

Testing was performed following CLSI guideline, EP09c 3rd edition. Samples ranging from 5.4 - 409.5 mg/L were tested using the K-*ASSAY*® CRP (Ver.2) assay on an Abbott Architect c8000 analyzer and compared to results from a predicate assay also using the same analyzer. Analysis yielded the following results:
y = K-*ASSAY*® CRP (Ver.2), x = predicate device
y = 1.005x – 0.002 r = 0.999 n = 175

Linearity

Testing was performed on an Abbott Architect c8000 analyzer following CLSI guideline EP06, 2nd edition. Testing the linear range of 4.6 - 441.2 mg/L yielded the following regression equation:
y = 0.9709x - 1.095, r = 0.999

Limit of Quantitation (LoQ)

The detection limits of the assay were evaluated based on CLSI guideline EP17-A2. The LoQ was defined as the concentration achieving within-laboratory precision of ≤ 20% CV across all 3 reagent lots, with the highest observed LoQ being 1.0 mg/L. However, the claimed LoQ for the K-*ASSAY*® CRP (Ver.2) is 5.0 mg/L.

Assay Range

As confirmed by linearity and LoQ testing, the assay range has been set as:
5 - 400 mg/L.

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Matrix Comparison

42 donor samples were each collected into 3 collection tubes to assess the effects of anticoagulants. Values of serum samples ranging from 5.1 - 399.1 mg/L were compared with values for plasma samples collected using Potassium-EDTA and Lithium-Heparin, yielding the following results by regression analysis:

K2-EDTA Plasma (y) vs Serum (x):
y = 1.007x - 0.141, r = 0.999

Li-Heparin Plasma (y) vs Serum (x):
y = 0.972x + 0.074, r = 0.999

Precision

Estimates of imprecision, based on CLSI recommendations, are consistent with typical performance.

Single-site precision was evaluated using 3 unique lots of K-*ASSAY*® CRP (Ver.2) on an Abbott Architect c8000 analyzer. 2 commercial controls and 5 human serum samples were analyzed in 2 runs per day, with 2 replicates per run, for 20 days.

Multisite precision was evaluated using 1 lot of K-*ASSAY*® CRP (Ver.2) on 3 Abbott Architect c8000 analyzers. 2 commercial controls and 5 human serum samples were analyzed in 1 run per day, with 5 replicates per run, for 5 days.

Data was evaluated using the CLSI approved guideline, EP05-A3 3rd edition, and representative comparative performance data appears in the tables below.

Single-Site Precision (Combined Data From 3 Lots)

			Within-Run		Between-Run		Within-Lot		Between-Lot		Total	
Sample	**Mean (mg/L)**	**N**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**
Control Level 1	9.8	240	0.2	1.7%	0.0	0.4%	0.2	1.7%	0.0	0.1%	0.2	1.7%
Control Level 2	31.7	240	0.3	1.1%	0.2	0.5%	0.4	1.1%	0.0	0.0%	0.4	1.1%
Sample 1	5.4	240	0.1	2.2%	0.0	0.0%	0.1	1.9%	0.1	1.2%	0.1	2.3%
Sample 2	11.1	240	0.1	1.2%	0.1	0.5%	0.1	1.3%	0.0	0.3%	0.1	1.3%
Sample 3	45.0	240	0.4	0.8%	0.3	0.6%	0.4	0.9%	0.1	0.1%	0.4	0.9%
Sample 4	196.5	240	1.8	0.9%	0.8	0.4%	1.8	0.9%	0.8	0.4%	1.9	1.0%
Sample 5	330.7	240	4.6	1.4%	1.3	0.4%	4.7	1.4%	0.0	0.0%	4.7	1.4%

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Multisite Precision (Combined Data From 3 Analyzers)

			Repeatability		Between-Run		Between-Day		Between-Site		Reproducibility	
Sample	**Mean (mg/L)**	**N**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**	**SD**	**CV %**
Control Level 1	10.0	75	0.1	1.1%	0.0	0.4%	0.1	1.1%	0.1	1.3%	0.2	1.7%
Control Level 2	31.4	75	0.2	0.7%	0.3	1.0%	0.4	1.2%	0.3	1.1%	0.5	1.6%
Sample 1	5.4	75	0.1	1.2%	0.0	0.0%	0.1	1.2%	0.1	1.1%	0.1	1.6%
Sample 2	11.1	75	0.1	1.0%	0.0	0.0%	0.1	1.0%	0.2	1.8%	0.2	2.0%
Sample 3	45.0	75	0.2	0.5%	0.2	0.4%	0.3	0.6%	0.4	0.9%	0.5	1.1%
Sample 4	200.6	75	1.3	0.7%	1.7	0.8%	2.1	1.1%	1.9	1.0%	2.9	1.4%
Sample 5	344.5	75	5.1	1.5%	3.7	1.1%	6.3	1.8%	5.8	1.7%	8.6	2.5%

Interference

Testing was performed on an Abbott Architect c8000 analyzer according to the CLSI EP07-3rd edition guideline with the following results.

Endogenous and Exogenous Substances

Results of studies conducted to evaluate the susceptibility of the method to interference from common or known endogenous and exogenous substances that could interfere with the assay are listed below. The criterion for no significant interference is recovery within 10% of the initial value (sample containing no interferent).

The following substances were tested up to the listed concentrations, and no significant interference was observed:

Endogenous Substances

Bilirubin C, (Conjugated)	40 mg/dL
Bilirubin F (Unconjugated)	40 mg/dL
Cholesterol	300 mg/dL
Hemoglobin	1,000 mg/dL
Intralipid	500 mg/dL
Rheumatoid Factor	1,000 IU/mL
Triglycerides	1,000 mg/dL

Exogenous Substances

Acetaminophen	1.5 mM
Amoxicillin	400 µmol/L
Aspirin (Acetylsalicylic Acid)	3.6 mM
Cephalexin	360 µmol/L
Fluconazole	480 µmol/L
Ibuprofen	2.5 mg/dL

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Methotrexate	1,400 µmol/L
Prednisolone	2 µmol/L
Vitamin C (Ascorbic Acid)	500 mg/L

Expected Values

For evaluation of infection, tissue injury, and inflammation disorders, the following suggested ranges from widely accepted literature references are used.[1,2,3]

≤ 5 mg/L indicates apparently healthy individuals

≥ 10 mg/L is clinically significant

As a verification, 168 normal serum samples taken from healthy individuals in the U.S. were tested with the K-*ASSAY*® CRP (Ver.2) assay based on CLSI C28-A3. All samples were run on an Abbott Architect c8000 analyzer. The results showed that 4 out of the 168 samples were >5.0 mg/L (2.4%).

1. U.S. FDA, *Review Criteria for Assessment of C-Reactive Protein (CRP), High Sensitivity C-Reaction Protein (hsCRP) and Cardiac C-Reaction Protein (cCRP) Assays*, rev. Sep 22, 2005.
2. Dati F., *et al*. *Consensus of a group of professional societies and diagnostic companies on guidelines for interim reference ranges for 14 proteins in serum based on the standardization against the IFCC/ BCR/ CAP reference material (CRM 470)*. European Journal of Clinical Chemistry and Clinical Biochemistry. 34(6):517-520, 1996.
3. Rifai, N. and Ridker, P.M. *Population distributions of C-reactive protein in apparently healthy men and women in the United States: Implication for clinical interpretation.* Clin Chem, 49(4):666-669, 2003.

9. Conclusion

The performance of the K-*ASSAY*® CRP (Ver.2) assay is substantially equivalent to other similar assays on the market.