February 23, 2024

Sebia
Karen Anderson
Director of Regulatory Affairs and Quality Assurance
1705 Corporate Drive Suite 400
Norcross, Georgia 30093

Re: K231601
Trade/Device Name: FLC Kappa, FLC Lambda
Regulation Number: 21 CFR 866.5550
Regulation Name: Immunoglobulin (Light Chain Specific) Immunological Test System
Regulatory Class: Class II
Product Code: DFH, DEH
Dated: January 12, 2024
Received: January 12, 2024

Dear Karen Anderson:

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,

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)*
K231601

Device Name
FLC Kappa
FLC Lambda

Indications for Use *(Describe)*
The FLC Kappa kit is intended for the quantification of Kappa free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used in conjunction with other laboratory and clinical findings.
For In Vitro Diagnostic Use only.

The FLC Lambda kit is intended for the quantification of Lambda free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used 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.

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."

510K SUMMARY (Summary of Safety and Effectiveness)

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

Submitter Name	Sebia, Inc.
Address	1705 Corporate Drive Suite 400 Norcross, Georgia 30093, USA
Contact	Karen Anderson, Dir of Regulatory, Sebia Inc. Phone: 1-800-835-6497 Fax: 770-446-8511 Email: karen.anderson@sebia-usa.com Matthew C Wagner, Scientific Affairs Specialist Phone 1-800-835-6497, 3752 Fax 770-446-8511 Email: matthew.wagner@sebia-usa.com
Date Prepared	February 16, 2024
Manufacturing	Sebia Parc Technologique Léonard de Vinci Rue Léonard de Vinci, CP 8010 LISSES, 91008 EVRY Cedex FRANCE Phone: (33) 1 69 89 80 80 Fax: (33) 1 69 89 78 78
Product Name	FLC Kappa FLC Lambda
Common Name	Light Chain immunological test system
Product Regulation No.	21CFR sec. 866.5550 - Immunoglobulin (light chain specific) immunological test system 21 CFR sec. 862.1660- Quality Control Material (assayed and unassayed)
Product Codes	DFH, Kappa antigen, antiserum, control DEH, Lambda, antigen, antiserum, control
Device classification and Panel Classification	Class II, Immunology (82)
Establishment Registration No.	8023024

1. DEVICE DESCRIPTIONS

The FLC Kappa and FLC Lambda test kits are intended for the quantification of free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure utilizing specific antibodies targeting anti-Kappa and anti-Lambda free light chains.

It is carried out in 8 successive steps:

- Incubation of the previously diluted samples and calibrators, in the wells of the microplate, where specific free light chain antibodies are fixed.
- Washing of the wells to remove elements that have not been fixed by the anti-free light chain antiserum.
- Incubation with an anti- light chain antiserum (Kit specific) conjugated to peroxidase.
- Washing of the wells to remove the excess of antiserum conjugated to peroxidase.
- Incubation with peroxidase substrate.
- Stopping of the enzymatic reaction with an acidic solution.
- Reading of the optical density by absorbance spectrophotometry at 450 nm of the colored product.
- Calculation of the free light chain concentration of the sample using a calibration curve obtained with calibrators that have been analyzed on the same microplate.

The devices in this submission are not materially changed from cleared under K210623.
The purpose for this submission is to:

- add aids in the monitoring of Multiple Myeloma and Immunoglobulin Light-Chain (AL-) amyloidosis to the intended use,
- extend shelf-life for FLC Kappa and FLC Lambda kits,
- add additional data for shelf-life of FLC Controls Level 1 and Level 2.

2. REAGENTS

REAGENTS AND MATERIALS SUPPLIED IN THE FLC KAPPA AND FLC LAMBDA KITS

ITEMS	PN 5102 FLC Kappa Kit	PN 5103 FLC Lambda Kit
Microplate Kappa 1 plate with 12 segments, 8 wells each	Microplate Kappa 1 plate with 12 segments, 8 wells each	Microplate Lambda 1 plate with 12 segments, 8 wells each
Dilution buffer (ready to use)	1 vial, 100 mL	1 vial, 100 mL
Wash solution (stock solution)	1 vial, 100 mL	1 vial, 100 mL
Calibrators (ready to use)	5 vials, 0.6 mL each Kappa Calibrators	5 vials, 0.6 mL each Lambda Calibrators
PER antiserum (ready to use)	1 vial, 12 mL Anti-Kappa – PER antiserum (ready to use)	1 vial, 12 mL Anti-Lambda – PER antiserum (ready to use)
Substrate	1 vial, 12 mL Substrate Kappa (ready to use)	1 vial, 12 mL Substrate Lambda (ready to use)
Stop solution (ready to use)	1 vial, 12 mL	1 vial, 12 mL

REAGENTS/SUPPLIES REQUIRED BUT NOT SUPPLIED IN THE KITS

SUPPLIES	SEBIA PRODUCT NUMBER
Densitometer for microplate reading by absorbance spectrophotometry at 450 nm.	
NON COATED ELISA PLATES (10), SEBIA, microplates with scored wells in order to complete segments when the forecasted number of samples per segment is fewer than 8, and frame to store the segments that have not been used.	PN 5303
Absorbent paper for removal the excess of wash solution from the wells of the microplate.	
Multichannel pipette.	
FLC CONTROL LEVEL 1	PN 5112
FLC CONTROL LEVEL 2	PN 5113

3. INDICATIONS FOR USE

FLC Kappa and FLC Lambda kits

The FLC Kappa kit is intended for the quantification of Kappa free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used in conjunction with other laboratory and clinical findings.
For *In Vitro* Diagnostic Use only.

The FLC Lambda kit is intended for the quantification of Lambda free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used in conjunction with other laboratory and clinical findings.
For *In Vitro* Diagnostic Use only.

Special conditions for use statements: For prescription use only.

Warning: The result of the FLC Kappa and FLC Lambda in a given specimen determined with assays and/or instrument platforms from different manufacturers can vary due to differences in assay methods and reagent
specificity. The results reported by the laboratory to the physician must include the identity of the 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 FLC Kappa level is changed, additional sequential testing should be carried out. Prior to changing assays, the laboratory MUST confirm baseline values for patients being serially monitored.

SUBSTANTIAL EQUIVALENCE INFORMATION

Predicate Device Name	Predicate Device 510(k) number	Regulation No.
The Binding Site Freelite® Human Kappa Free Kit for use on the Siemens BN™ II	K031016	866.5550
The Binding Site Freelite® Human Lambda Free Kit for use on the Siemens BN™ II	K031016	866.5550

4. COMPARISON WITH PREDICATE DEVICE

Kit Similarities (Table A).

Similarities		
Table A	**Candidate Device** FLC Kappa FLC Lambda	**Predicate** The Binding Site Freelite® Human Kappa Free and Freelite® Human Lambda Free kits for use on the Siemens BN™ II (K031016)
Analyte	Kappa: Kappa FLC Lambda: Lambda FLC	Same
Measurement	Quantitative	Same

Kit Differences (Table B)

	Differences	
Table B	**Candidate Device**	**Predicate Device**
Indications for Use	The FLC Kappa kit is intended for the quantification of Kappa free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used in conjunction with other laboratory and clinical findings. For *In Vitro* Diagnostic Use only. Special conditions for use statements: For prescription use only.	Kappa: This kit is intended for the quantitation of kappa free light chains in serum and urine on the Siemens BN™ II. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, Waldenstrom's macroglobulinemia, AL amyloidosis, light chain deposition disease and connective tissue diseases such as systemic lupus erythematosus in conjunction with other laboratory and clinical findings

	The FLC Lambda kit is intended for the quantification of Lambda free light chains in human serum from adults with an Enzyme-Linked Immunosorbent Assay (ELISA) procedure. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma and AL amyloidosis. It must be used in conjunction with other laboratory and clinical findings. For *In Vitro* Diagnostic Use only Special conditions for use statements: For prescription use only..	Lambda: This kit is intended for the quantitation of lambda free light chains in serum and urine on the Siemens BN™ II. Measurement of free light chains aids in the diagnosis and monitoring of multiple myeloma, lymphocytic neoplasms, Waldenstrom's macroglobulinemia, AL amyloidosis, light chain deposition disease and connective tissue diseases such as systemic lupus erythematosus in conjunction with other laboratory and clinical findings.
Specimen Type	Human Serum	Human Serum, Human Urine
Detection Method	Enzyme-Linked Immunosorbent Assay (ELISA)	Nephelometric
Detection Antibody	Kappa : Sandwich ELISA with polyclonal rabbit anti- human kappa free light chains coated on the well of the microplate (capture antibody) and polyclonal rabbit anti-human kappa light chain conjugated to horseradish peroxidase (HRP) (detection antibody) Lambda: Sandwich ELISA with polyclonal rabbit anti-human lambda free light chain coated on the well of the microplate (capture antibody) and polyclonal rabbit anti-human lambda light chain conjugated to horseradish peroxidase (HRP) (detection antibody)	Kappa: Polyclonal sheep anti-human kappa antibody coated with latex particles Lambda: Polyclonal sheep anti-human Lambda antibody coated with latex particles
Analytical Measuring ranges	Kappa Standard dilution (1/1000) 4.5 to 76.2 mg/L (dilution scheme 1/250 to 1/100 000) Lambda Standard dilution (1/1000) 3.8 to 66.8 mg/L (dilution scheme 1/250 to 1/100 000)	Kappa Standard dilution (1/100) 5.9 to 190 mg/L (dilution scheme 1/5 to 1/8000) Lambda Standard dilution (1/100) 5.0 to 160 mg/L (dilution scheme 1/5 to 1/8000)
Reference Interval	Kappa: 6.4 to 17.4 mg/L. Lambda: 8.4 to 21.8 mg/L. Ratio: 0.46 to 1.51	Kappa: 3.30 to 19.40 mg/L Lambda: 5.71 to 26.30 mg/L Ratio: 0.26-1.65

Calibrators:

Similarities		
Item	Candidate	Predicate
Reference Material	Internal Reference preparation	Same

Differences		
Item	Candidate	Predicate
Number of levels	5	One

5. PERFORMANCE DATA

Performance Data:
Extended indication for aids in the monitoring of multiple myeloma and AL amyloidosis.
Extended shelf-life for FLC Kappa and FLC Lambda kits and additional data for shelf-life of FLC controls Level 1 and Level 2.

See submissions K210623 for previously documented analytical and clinical studies:
Precision and Reproducibility
Linearity/assay
Limit of Blank (LOB) / Limit of Detection (LOD) / Limit of Quantitation (LOQ)
Hook Effect (Antigen Excess)
Traceability
Analytical specificity: Biological and Drug Interferences
In-use Stability
Expected values/ Reference range
Comparison studies: Quantitative and Qualitative comparison
Clinical Study: Diagnosis of multiple myeloma and AL amyloidosis

a)Clinical Study

Monitoring of multiple myeloma and AL amyloidosis

Multiple myeloma

A total of 551 follow up samples from 235 unique subjects diagnosed with multiple myeloma and with expanded racial and ethnic diversity (Caucasian, African American, Hispanic, Asian) were included in the clinical study for FLC Kappa and FLC Lambda assays.
The concordance of the results obtained with FLC Kappa and FLC Lambda kits for monitoring the Multiple Myeloma with other tests and clinical assessment was evaluated based on criteria of the IMWG (International Myeloma Working Group).

The obtained results are as follows:

Response based on FLC Assays	Clinical Assessment				
	Good Response*	Moderate Response**	Stable Disease (SD)	Progressive Disease (PD)	Total
Good Response*	78	0	0	1	79
Moderate Response**	0	82	14	0	96
Stable Disease (SD)	0	20	310	12	342
Progressive Disease (PD)	0	1	5	28	34
Total	78	103	329	41	551
Concordance (n/N) (95% CI)	100.0% (78/78) (100.0%; 100.0%)	79.6% (82/103) (71.8%; 87.4%)	94.2% (310/329) (91.7%; 96.7%)	68.3% (28/41) (54.0%; 82.5%)	**90.4% (498/551) (87.9%; 92.8%)**

** Including subjects with Stringent Complete Response (sCR) and Complete Response (CR).*
*** Including subjects with Very Good Partial Response (VGPR) and Partial Response (PR).*

The clinical sensitivity and specificity for the monitoring events regarding "Progression" and "No-progression" based on criteria of the IMWG were evaluated with FLC Kappa and Lambda kits. The obtained results are as follows:

Response based on FLC Assays	Clinical Assessment		
	Progression	No Progression	Total
Progression*	28	6	34
No Progression**	13	504	517
Total	41	510	551
Clinical Sensitivity: 68.3% (28/41) (95% CI: 54.0% to 82.5%) Clinical Specificity: 98.8% (504/510) (95% CI: 97.9% to 99.8%)			

** Progression (PD- Progressive Disease): (≥ 25% increase of M-protein AND increase of M-protein ≥ 0.5 g/L) OR (≥ 25% increase of rd_dFLC AND d_dFLC increase > 100 mg/L).*
*** No Progression: all other cases.*

AL-amyloidosis

A total of 190 follow up samples from 87 unique subjects diagnosed with AL-Amyloidosis and with expanded racial and ethnic diversity (Caucasian, African American, Hispanic) were included in the clinical study for FLC Kappa and FLC Lambda assays.
The concordance of the results obtained with FLC Kappa and FLC Lambda kits for monitoring the AL-Amyloidosis with other tests and clinical assessment was evaluated based on the consensus guideline for assessment of treatment response published by Comenzo *et al*., 2012, reiterated by Palladini *et al*., 2012 and updated in 2021 (Mode No. 1), and published by Kumar *et al*., 2022 as the National Comprehensive Cancer Network (NCCN) guidelines for AL-Amyloidosis (Mode No. 2).

The obtained results are as follows:

Response based on FLC Assays	Clinical Assessment (Evaluation mode No. 1)					
	Complete Response (CR)	Very Good Partial Response (VGPR)	Partial Response (PR)	Stable Disease / No Response (SD/NR)	Progressive Disease (PD)	Total
Complete Response (CR)	17	2	2	0	1	22
Very Good Partial Response (VGPR)	4	74	14	14	2	108
Partial Response (PR)	1	2	9	1	2	15
Stable Disease / No Response (SD/NR)	0	2	4	20	2	28
Progressive Disease (PD)	0	2	0	0	15	17
Total	22	82	29	35	22	190
Concordance (n/N) (95% CI)	77.3% (17/22) (59.8%; 94.8%)	90.2% (74/82) (83.8%; 96.7%)	31.0% (9/29) (14.2%; 47.9%)	57.1% (20/35) (40.7%; 73.5%)	68.2% (15/22) (48.7%; 87.6%)	**71.1% (135/190) (64.6%; 77.5%)**

Response based on FLC Assays	Clinical Assessment (Evaluation mode No. 2)					
	Complete Response (CR)	Very Good Partial Response (VGPR)	Partial Response (PR)	Stable Disease / No Response (SD/NR)	Progressive Disease (PD)	Total
Complete Response (CR)	6	8	2	0	0	16
Very Good Partial Response (VGPR)	9	73	14	15	3	114
Partial Response (PR)	0	3	9	1	2	15
Stable Disease / No Response (SD/NR)	0	2	4	20	2	28
Progressive Disease (PD)	0	2	0	0	15	17
Total	15	88	29	36	22	190
Concordance (n/N) (95% CI)	40.0% (6/15) (15.2%; 64.8%)	83.0% (73/88) (75.1%; 90.8%)	31.0% (9/29) (14.2%; 47.9%)	55.6% (20/36) (39.3%; 71.8%)	68.2% (15/22) (48.7%; 87.6%)	**64.7% (123/190) (57.9%; 71.5%)**

The clinical sensitivity and specificity for the monitoring events regarding “Progression” and “No-progression” based on evaluation modes No. 1 and No. 2 were evaluated with FLC Kappa and Lambda kits. The obtained results are as follows:

Response based on FLC Assays	Clinical Assessment (Evaluation mode No. 1)		
	Progression	No Progression	Total
Progression*	15	2	17
No Progression**	7	166	173
Total	22	168	190
Clinical Sensitivity: 68.2% (15/22) (95% CI: 48.7% to 87.6%) Clinical Specificity: 98.8% (166/168) (95% CI: 97.2% to 100.0%)			

Response based on FLC Assays	Clinical Assessment (Evaluation mode No. 2)		
	Progression	No Progression	Total
Progression*	15	2	17
No Progression**	7	166	173
Total	22	168	190
Clinical Sensitivity: 68.2% (15/22) (95% CI: 48.7% to 87.6%) Clinical Specificity: 98.8% (166/168) (95% CI: 97.2% to 100.0%)			

** Progression (PD – Progressive Disease):*
- from CR: any detectable M-protein OR abnormal FLC ratio (involved FLC must be at least doubling from normal range),
- from PR or VGPR: 50% increase in serum M-protein to > 5 g/L OR 50% increase in urine M-protein to > 200 mg/day (a visible peak must be present); OR involved FLC increase greater than 50% to 100 mg/L at any time.
*** No Progression: all other cases.*

b) Stability

Shelf-life studies were conducted using the FLC Kappa and FLC Lambda kits and FLC controls Level 1 and Level 2. All results met stability acceptance criteria and product stability claims as listed in the tables below:

Stability of Kit (FLC Kappa and FLC Lambda)

Kit	Shelf Life
FLC Kappa	12 months at 2 - 8 °C
FLC Lambda	12 months at 2 - 8 °C

Stability of Controls (FLC Control Level 1 and FLC Control Level 2)

Kit	Shelf Life		
	Claimed Shelf Life	Real time stability (time point available)	Claimed Stability
FLC Control Level 1	4 years at 2 - 8 °C	3 years at 2 - 8 °C	2 years at 2 - 8 °C
FLC Control Level 2	3 years at 2 - 8 °C	3 years at 2 - 8 °C	2 years at 2 - 8 °C

6. CONCLUSION

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.