November 1, 2019

Sebia
Karen Anderson
Director of Regulatory
1705 Corporate Drive Suite 400
Norcross, Georgia 30093

Re: K192095
Trade/Device Name: CAPI 3 Immunotyping, Capillarys 3 Tera
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: CEF, DEH, DFH, CFF
Dated: July 31, 2019
Received: August 5, 2019

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 (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 located 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.

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

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 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,

Takeesha Taylor-Bell
Acting Deputy Director
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CAPI 3 IMMUNOTYPING

Indications for Use *(Describe)*
The CAPI 3 IMMUNOTYPING kit is designed for the qualitative detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS 3 TERA instrument, SEBIA, for capillary electrophoresis. It is used in conjunction with the CAPI 3 PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).
The CAPILLARYS 3 TERA instrument performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each urine or serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains, respectively.
The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm.
The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspect monoclonal proteins.

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.

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, Director of Regulatory Phone: 1-800-835-6497 Fax: 770-446-8511 Email: karen.anderson@sebia-usa.com Matthew C. Wagner, Ph.D Scientific Affairs Specialist Email: Matthew.wagner@sebia-usa.com Phone: 1-800-835-6497, 3752
Date Prepared	October 7, 2019
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	CAPI 3 IMMUNOTYPING (PN 2600) using CAPILLARYS 3 TERA instrument (PN 1246)
Common Name	Monoclonal Immunoglobulins by Capillary Electrophoresis
Product Regulation No.	21 CFR Part 866.5510, 866.5550, 866.1630,
Classification Product Code	CFF

Subsequent Product Codes	DFH, DEH, CEF
Device classification	Class II (Test System), Class I (Controls Electrophoretic Protein Fractionation)
Establishment Registration No.	8023024

This submission is to support the additional of new matrix (Urine) to Sebia's previously cleared reagent/ instrument combination CAPI 3 IMMUNOTYPING using the CAPILLARYS 3 TERA, K161928.

The predicate device used in this submission is Sebia's CAPILLARYS IMMUNOTYPING using the CAPILLARYS 2, K130500

1. DEVICE DESCRIPTION

The capillary electrophoresis provides complete automation with fast separation and good resolution. This electrokinetic separation technique is carried out in a silica glass tube (i.e., capillary) with internal diameter lower than 100 µm filled with a buffer composed of electrolytes.

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Separation occurs according to the electrolyte pH and electroosmotic flow. The CAPILLARYS 3 TERA instrument has silica capillaries functioning in parallel allowing 12 simultaneous analyses.

In capillary electrophoresis, abnormal fractions detected in serum or urine protein electrophoregrams, primarily those in the beta globulin and gamma globulin zones, are always suspect of being monoclonal proteins (M-proteins, paraproteins, monoclonal immunoglobulins). With the CAPI 3 IMMUNOTYPING procedure, the immunotyping procedure uses specific antibodies to identify these abnormal fractions.

In immunotyping a sample dilution is prepared and injected at the anodic end of six capillaries. The reference pattern (ELP pattern), which is a complete electrophoretic pattern of the sample's proteins, is obtained by mixing the sample with the ELP solution and injection into the 1st capillary. The antisera patterns are obtained by sample aspiration into the 5 subsequent capillaries. Previously diluted samples are mixed with specific antisera against gamma (Ig G), alpha (Ig A), mu (Ig M) heavy chains, and free and bound Kappa and Lambda light chains. Protein separation is performed in a high voltage electrical field. The separated proteins are detected using absorbance at 200 nm at the cathodic end of the capillary. After the analysis, the capillaries are immediately washed with a wash solution and filled with buffer which prepares the capillaries for the next analysis.

The immunotyping is performed in four automated steps:

1. Dilution of serum or urine samples with a specific diluent in the pre-dilution well of the reagent cup. This dilution is made according to the sample's immunoglobulin concentration.
2. Mixing diluted serum sample with specific antisera. The antigen - antibody complex is formed rapidly in liquid medium without the need for extra incubation step or removal of the immune complexes.
3. Injection of the prepared samples with simultaneous aspiration into 6 capillaries at the anodic end. Protein separation occurs when a high voltage field is applied to the alkaline buffer. The separated proteins are detected using absorbance at 200 nm at the cathodic end of the capillary.
4. Overlay of the ELP pattern on the antisera patterns (Ig G, Ig A, Ig M, Kappa and Lambda) allows characterization of suspected monoclonal component.

Reagents:

CAPI 3 IMMUNOTYPING KIT

ITEMS	PN 2600
Sample diluent (ready to use)	1 vial, 60 mL
Pierceable cap for the Sample diluent vial	1 cap
Rack with ELP solution and antiserum tubes	
ELP solution (ready to use)	1 vial, 1.2 mL
Mammalian immunoglobulins antihuman gamma heavy chains (ready to use)	1 vial, 1.2 mL
Mammalian immunoglobulins antihuman alpha heavy chains (ready to use)	1 vial, 1.2 mL
Mammalian immunoglobulins antihuman mu heavy chains (ready to use)	1 vial, 1.2 mL
Mammalian immunoglobulins antihuman kappa (free and bound) light chains (ready to use)	1 vial, 1.2 mL
Mammalian immunoglobulins antihuman lambda (free and bound) light chains (ready to use)	1 vial, 1.2 mL

Additional reagents not included in the CAPI 3 IMMUNOTYPING KIT

ITEMS	PN	COMPONENTS
CAPI 3 PROTEIN(E) 6	2503	3 vials buffer, 700 mL each 4 filters

CAPICLEAN CAPILLARYS 3	2060	1 vial, 25 mL
CAPILLARYS 3 WASH SOLUTION	2062	1 vial, 75mL
CAPI 3 DISPOSABLES KIT	2582	24 packs of 14 reagent cups
TEST TUBES	9214	200 of 100mm-tubes
CAPI 3 BINS FOR USED REAGENT CUPS	2581	5 units
CAPI 3 URINE KIT	2513	1 Vial , 480 mL

2. INDICATIONS FOR USE

The CAPI 3 IMMUNOTYPING kit is designed for the qualitative detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS 3 TERA instrument, SEBIA, for capillary electrophoresis. It is used in conjunction with the CAPI 3 PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).

The CAPILLARYS 3 TERA instrument performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each urine or serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains, respectively.

The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm. The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspect monoclonal proteins.

For In Vitro Diagnostic Use.

3. TECHNOLOGICAL CHARACTERISTICS

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in free solution. With this technique, charged molecules are separated by their electrophoretic mobility in an alkaline buffer with a specific pH. Protein separation is performed in a high voltage electrical field. The separated proteins are directly detected using absorbance at 200 nm at the cathodic end of the capillary. Separation occurs according to the electrolyte pH and is driven by electroosmotic flow. The CAPILLARYS 3 TERA instrument has silica capillaries functioning in parallel allowing 12 simultaneous analyses.

With the CAPI 3 IMMUNOTYPING procedure, the immunotyping using specific antibodies is performed to identify abnormal fractions in serum or urine protein profiles. The immunotyping is performed in four automated steps:

1. Dilution of serum or dialyzed urine samples with a specific diluent in the predilution well of the reagent cup. This dilution is made according to the sample's immunoglobulin concentration.

2. Mixing diluted serum or urine sample with specific antisera. The antigen - antibody complex is formed rapidly in liquid medium without the need for extra incubation step or removal of the immune complexes.
3. Injection of prepared samples with simultaneous aspiration into 6 capillaries at their anodic end. Protein separation occurs when a high voltage field is applied to the alkaline buffer. The separated proteins are detected using absorbance at 200 nm at the cathodic end of the capillary.
4. Overlay of the ELP pattern on the antisera patterns (Ig G, Ig A, Ig M, Kappa and Lambda) allows characterization of suspected monoclonal component.

2. SUBSTANTIAL EQUIVALENCE INFORMATION:

Predicate Device Name	Predicate Device 510(k) number
CAPILLARYS IMMUNOTYPING using CAPILLARYS 2 / CAPILLARYS 2 FLEXPIERCING INSTRUMENT	K130500
CAPI 3 IMMUNOTYPING using the CAPILLARY 3 TERA INSTRUMENT (SERUM MATRIX)	K161928

This submission is to support the additional of new matrix (Urine) to Sebia's previously cleared reagent/ instrument combination CAPI 3 IMMUNOTYPING using the CAPILLARYS 3 TERA, K161928.

The predicate device used in this submission is Sebia's CAPILLARYS IMMUNOTYPING using the CAPILLARYS 2, K130500

Table A.
Similarities and differences between the candidate device (CAPI 3 IMMUNOTYPING and the predicate device (CAPILLARYS IMMUNOTYPING).

.

Table A	SEBIA CAPILLARYS IMMUNOTYPING (K) 130500	SEBIA CAPI 3 IMMUNOTYPING (Additional of Urine)
Intended Use	The CAPILLARYS IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS, the CAPILLARYS 2 and the CAPILLARYS 2 FLEX-PIERCING, SEBIA, for capillary electrophoresis. It is used in conjunction with the SEBIA CAPILLARYS PROTEIN(E) 6 kit designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9). The CAPILLARYS, CAPILLARYS 2 and the CAPILLARYS 2 FLEX-PIERCING perform all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each urine or serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains, respectively. The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm. The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspect monoclonal proteins. For *In Vitro* Diagnostic Use.	The CAPI 3 IMMUNOTYPING kit is designed for the qualitative detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS 3 TERA instrument, SEBIA, for capillary electrophoresis. It is used in conjunction with the CAPI 3 PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9). The CAPILLARYS 3 TERA instrument performs all procedural sequences automatically to obtain a protein profile for qualitative analysis. Each urine or serum sample is mixed with individual antisera that are specific against gamma (Ig G), alpha (Ig A) and mu (Ig M) heavy chains, and kappa (free and bound) light chains and lambda (free and bound) light chains, respectively. The proteins, separated in silica capillaries, are directly detected by their absorbance at 200 nm. The electrophoregrams are evaluated visually to detect the presence of specific reactions with the suspect monoclonal proteins. For *In Vitro* Diagnostic Use.
Separation system	Free solution capillary electrophoresis (FSCE): protein separation in an alkaline buffer (pH 9.9) according to their charge, to the electrolyte pH and electroosmotic flow. Fast separation and good resolution. Electrophoregrams show separated fractions according to their charge.	Same
Sample Type	Serum and Urine	Same

Results	Qualitative	Same
Reagent	CAPILLARYS IMMUNOTYPING Kit (PN 2100) : Antisera segment containing : ELP solution mammalian immunoglobulins antihuman gamma heavy chains mammalian immunoglobulins antihuman alpha heavy chains mammalian immunoglobulins antihuman mu heavy chains mammalian immunoglobulins antihuman kappa (free and bound) light chains mammalian immunoglobulins antihuman lambda (free and bound) light chains sample diluent	CAPI 3 IMMUNOTYPING Kit (PN 2600) : Sample diluent Rack with ELP solution tube and antiserum tubes : mammalian immunoglobulins antihuman gamma heavy chains mammalian immunoglobulins antihuman alpha heavy chains mammalian immunoglobulins antihuman mu heavy chains mammalian immunoglobulins antihuman kappa (free and bound) light chains mammalian immunoglobulins antihuman lambda (free and bound) light chains
Urine Kit	CAPILLARYS/MINICAP URINE KIT PN 2013 1 Vial 480 mL	CAPI 3 URINE KIT *PN 2513 1 Vial , 480 mL Reagent same, PN to reflect Capi 3 part number sequence.

Table A (continued)	**SEBIA CAPILLARYS IMMUNOTYPING (K) 130500**	**SEBIA CAPI 3 IMMUNOTYPING**
Instrument	SEBIA CAPILLARYS 2 FLEX-PIERCING instrument, PN 1227 SEBIA CAPILLARYS 2 instrument, PN 1222	SEBIA CAPILLARYS 3 TERA instrument, PN 1246
Analysis throughput	16 analyses / 2hour	21 anlaysis / 2hours
Interface	PC interface	PC interface + touch screen
Temperature Control	By Peltier device	Same
Detection system	Deuterium lamp	Deuterium lamp and LED
Software for data processing	SEBIA PHORESIS™ software	Same
Firmware	Included into the PHORESIS software	Included into the instrument

Number of separation units	8 parallel capillaries	12 parallel capillaries
Samples tubes	uncapped tubes or capped tubes depending on the procedure	Same
Samples identification	Yes (Bar code reading on both sample racks and tubes)	Yes (Bar code reading on sample tubes and RFID labels on sample racks)
Reagent identification	No	Yes (RFID labels on reagent vials)
Introduction of the samples into the automatic system	Primary capacity of 13 tubes for IT technique (i.e. 13 sample racks), uninterrupted throughput on sample racks. Only position 1 on the sample rack contains sample tube.	Primary maximal capacity of 120 tubes (i.e. 15 sample racks), uninterrupted throughput on sample racks (8 positions available).
Reagent bay : main compartement	CAPILLARYS 2 : Contains one vial of water, wash solution and buffer container. CAPILLARYS 2 FLEX-PIERCING : Contains one vial of water, wash solution, hemolyzing solution (for Hb and Hb A1c techniques) and buffer container.	Up to 4 analysis buffers or hemolysing solutions (identified by RFID labels); 1 waste container, 1 container for, 1 container for the wash solution
Reagent bay : secondary compartement	NA	Up to 3 vials and 1 rack with immunotyping reagents (all RFID tagged) in temperature controlled environment (< 15 °C); 1 RFID labeled vial and three tubes (for maintenance solutions) at room temperature
Dimensions	L. 95 cm x H. 39 cm x D. 63 cm	L. 90 cm x H. 54 cm x D. 67 cm
Weight	50 kg	75 kg

3. Performance Data:

a. Repeatability

Four (4) different urine samples with monoclonal proteins including Bence Jones proteins were run using the CAPI 3 IMMUNOTYPING URINE procedure on all capillaries of the same CAPILLARYS 3 TERA instrument and with one lot of CAPI 3 IMMUNOTYPING kit. Each sample was analyzed with each reagent (ELP solution, Anti-Ig G, Anti-Ig A, Anti-Ig M,Anti-Kappa and Anti-Lambda) on all capillaries, including 2 runs per reagent. In this study all dilution programs were tested.For each tested reagent, all samples gave concordant results within run and between capillaries**.**

b. Reproducibility between lots and instruments

Three (3) different urine samples with monoclonal proteins including Bence Jones proteins were run using the CAPI 3 IMMUNOTYPING URINE procedure on 3 CAPILLARYS 3 TERA instruments and with 3 lots of CAPI 3 IMMUNOTYPING kit. Each sample was analyzed on 18 runs over 5 working days (at 2 different times of the day). In this study, all dilution programs were tested.
All samples gave concordant results for all runs on the 3 CAPILLARYS 3 TERA instruments and with the 3 lots of CAPI 3 IMMUNOTYPING kit.

c. Sensitivity

Serial dilutions were prepared in normal urine with three pathological urine samples all exhibiting monoclonal components and analyzed using the CAPI 3 IMMUNOTYPING URINE procedure.
The results are summarized below**:**

Sample	Monoclonal protein		Monoclonal protein concentration		Detection limit	
	Type		g/L	mg/dL	g/L	mg/dL
A	Lambda free	Lambda	2.432	243.2	0.010	1.0
C	Kappa free	Kappa	0.946	94.6	0.030	3.0
D	Ig G, Lambda	Gamma	0.118	11.8	0.004	0.4
		Lambda			0.004	0.4

d. Sample Stability Stability at 2-8 ºC

Ten (10) urine samples including normal and pathological urine samples were analyzed at the beginning of the study (reference) and after 1 week storage at 2 - 8°C (test), with the CAPI 3 IMMUNOTYPING URINE procedure performed with the CAPILLARYS 3 TERA instrument. The results obtained comply with the acceptance criteria defined by SEBIA of the CAPI 3 IMMUNOTYPING URINE procedure performed with the CAPILLARYS 3 TERA instrument. Urine samples can be stored for 1 week between 2 and 8 °C.

Stability - 70 / - 80 °C

Ten (10) urine samples including normal and pathological urine samples were analyzed at the beginning of the study (reference) and after 1 month storage at - 70 / - 80 °C (test), with the CAPI 3 IMMUNOTYPING URINE procedure performed with the CAPILLARYS 3 TERA instrument**.**
The results obtained comply with the acceptance criteria defined by SEBIA of the CAPI 3 IMMUNOTYPING URINE procedure performed with the CAPILLARYS 3 TERA instrument.
Urine samples can be stored for 1 month between - 70 and - 80 °C.

e. Kit Stability

CAPI 3 IMMUNOTYPING sample diluent	2 years at 2 - 30 ˚C
CAPI 3 IMMUNOTYPING ELP solution	2 years at 2 - 8 ˚C
CAPI 3 IMMUNOTYPING antisera	2 years at 2 - 8 ˚C

On- Board Stability CAPI 3 IMMUNOTYPING sample diluent CAPI 3 IMMUNOTYPING ELP solution CAPI 3 IMMUNOTYPING antisera	2 months

f. Accuracy/Concordance

The accuracy study included 52 urines samples composed of 8 urine samples without monoclonal component and 44 urine samples with monoclonal component including Bence Jones proteins. The samples were tested using the CAPI 3 IMMUNOTYPING URINE procedure performed with the CAPILLARYS 3 TERA instrument (test technique) and the CAPILLARYS IMMUNOTYPING URINE procedure performed with the CAPILLARYS 2 instrument (reference technique). All electrophoregrams were evaluated visually for the qualitative results.
This study demonstrated a 100 % agreement between the two techniques.

Qualitative Results	Number of urine samples	Complete Agreement
IgG Lambda	5	Complete Agreement
IgG Kappa	2	Complete Agreement
IgG Lambda with Lambda free	4	Complete Agreement
IgG Kappa with Kappa free	2	Complete Agreement
Lambda free	19	Complete Agreement
Kappa free	8	Complete Agreement
IgM Kappa with Kappa free	2	Complete Agreement
IgA Lambda	1	Complete Agreement
IgA Lambda with Lambda free	1	Complete Agreement
Without Monoclonal	8	Complete Agreement
Grand Total	52	Complete Agreement

4. Conclusion:

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