DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 21, 2016

SEBIA, INC.
Karen Anderson, MT (ASCP)
Director of Technical Training and Regulatory
Suite 400, 1705 Corporate Drive
Norcross, GA 30093

Re: K161928
Trade/Device Name: CAPI 3 IMMUNOTYPING, CAPILLARYS 3 TERA, IT/IF Control
Regulation Number: 21 CFR § 866.5510
Regulation Name: Immunoglobulins (A, G, M, D, E) Immunological Test Systems
Regulatory Class: Class II
Product Code: CFF - Immunoelectrophoretic, Immunoglobulins (G, A, M)
Dated: December 15, 2016
Received: December 19, 2016

Dear Ms. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Kelly Oliner -S

For
Leonthena Carrington, MBA, MS, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161928

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 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 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161928

Device Name
IT / IF Control

Indications for Use *(Describe)*
The IT / IF Control is designed to quality control the qualitative detection and characterization of human monoclonal immunoglobulins (Ig G, Ig A, Ig M, Kappa and Lambda) with the electrophoresis methods :
- Immunotyping performed using capillary electrophoresis on SEBIA CAPILLARYS 2, CAPILLARYS 2 FLEX-PIERCING and CAPILLARYS 3 TERA instruments and on SEBIA MINICAP instrument,
- Immunofixation methods : SEBIA HYDRAGEL IF, HYDRAGEL IF Penta, HYDRAGEL BENCE JONES (Standard mask and Dynamic mask) performed using the HYDRASYS and HYDRASYS 2 instruments and the K20 electrophoresis chamber.

The IT / IF Control is designed for laboratory use. It should be used (with its barcode label for CAPILLARYS and MINICAP procedures) like a human serum sample.
The electrophoretic pattern obtained is specific for each batch of IT / IF control.

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)

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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 Technical and QA Phone: 1-800-835-6497 Fax: 770-446-8511 Email: karen.anderson@sebia-usa.com Aigars Brants, Ph.D, Scientific Affairs Officer Phone 1-800-835-6497 Fax 770-446-8511 Email: aigars.brants@sebia-usa.com
Date Prepared	October 6, 2016 / **Revision Dec 14, 2016**
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) IT / IF Control (PN 4788) 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, 862.1660
Product Codes	CFF, DFH, DEH, CEF, JJY
Device classification	Class II (Test System), Class I (Controls Electrophoretic Protein Fractionation)
Establishment Registration No.	8023024

Predicate Device Name	Predicate Device 510(k) number
CAPILLARYS IMMUNOTYPING	K130500
CAPILLARYS 2 / CAPILLARYS 2 FLEX-PIERCING	K130500
IT / IF CONTROL	K130500

1. DEVICE DESCRIPTION

CAPILLARYS 3 TERA INSTRUMENT

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in liquid 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.

CAPI 3 IMMUNOTYPING KIT

In CAPI 3 MMUNUOTYPING kit contains the sample diluent and specific antisera against gamma (Ig G), alpha (Ig A), mu (Ig M) heavy chains, and free and bound Kappa and Lambda light chains. 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 separation is performed in a high voltage electrical field and detected using absorbance at 200 nm.

IT/IF CONTROL

The IT / IF control contains three monoclonal proteins which can be used as a qualitative control with the CAPI IMMUNOTYPING kit on the CAPILLARYS 3 TERA instrument.

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	2580	10 packs of 14 reagent cups 5 bins for used reagent cups
TEST TUBES	9214	200 of 100mm-tubes
CAPI 3 BINS FOR USED REAGENT CUPS	2581	5 units

2. INDICATIONS FOR USE

The CAPI 3 IMMUNOTYPING kit is designed for the qualitative detection and the characterization of monoclonal proteins (immunotyping) in human 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 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 IT / IF Control is designed to quality control the qualitative detection and characterization of human monoclonal immunoglobulins (Ig G, Ig A, Ig M, Kappa and Lambda) with the electrophoresis methods:
- Immunotyping performed using capillary electrophoresis on SEBIA CAPILLARYS 2, CAPILLARYS 2 FLEX-PIERCING and CAPILLARYS 3 TERA instruments and on SEBIA MINICAP instrument,
- Immunofixation methods: SEBIA HYDRAGEL IF, HYDRAGEL IF Penta, HYDRAGEL BENCE JONES (Standard mask and Dynamic mask) performed using the HYDRASYS and HYDRASYS 2 instruments and the K20 electrophoresis chamber.

The IT / IF Control is designed for laboratory use. It should be used (with its barcode label for CAPILLARYS and MINICAP procedures) like a human serum sample.
The electrophoretic pattern obtained is specific for each batch of IT / IF control.

For *In Vitro* Diagnostic Use.

3. TECHNOLOGICAL CHARACTERISTICS

The CAPILLARYS 3 TERA instrument uses the principle of capillary electrophoresis in liquid 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 protein profiles. The immunotyping is performed in four automated steps:

1. Dilution of serum 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.
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	K130500
CAPILLARYS 2 / CAPILLARYS 2 FLEX-PIERCING	K130500
IT / IF CONTROL	K130500

The technological characteristics of the CAPI 3 IMMUNOTYPING procedure using the CAPILLARYS 3 TERA instrument (candidate device) utilizes the same principles of capillary electrophoresis in an alkaline buffer reading at a wavelength of 200nm as the CAPILLARYS IMMUNOTYPING procedure (predicate device). *The CAPILLARYS 3 TERA using the CAPI 3 IMMUNOTYPING procedure follow the FDA guidance document, Replacement Reagent and Instrument Family Policy.*

Table A.

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

Both are members of the Sebia CAPILLARYS family of instruments.

Table A	SEBIA CAPILLARYS IMMUNOTYPING (K) 130500	SEBIA CAPI 3 IMMUNOTYPING
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 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 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
Reagent	CAPILLARYS IMMUNOTYPING Kit (PN 2100) : Antisera segment containing : ELP solution mammalian immunoglobulins anti-human gamma heavy chains mammalian immunoglobulins anti-human alpha heavy chains mammalian immunoglobulins anti-human mu heavy chains mammalian immunoglobulins anti-human kappa (free and bound) light chains mammalian immunoglobulins anti-human 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 anti-human gamma heavy chains mammalian immunoglobulins anti-human alpha heavy chains mammalian immunoglobulins anti-human mu heavy chains mammalian immunoglobulins anti-human kappa (free and bound) light chains mammalian immunoglobulins anti-human lambda (free and bound) light chains

Table A	SEBIA CAPILLARYS IMMUNOTYPING (K) 130500	SEBIA CAPI 3 IMMUNOTYPING
Instrument	SEBIA CAPILLARYS 2 FLEXPIERCING instrument, PN 1227 SEBIA CAPILLARYS 2 instrument, PN 1222	SEBIA CAPILLARYS 3 TERA instrument, PN 1246
Sample throughput	8 analyses / hour	21 (samples) analysis/ 2 hours
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 compartment	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

Table B.
Similarities and differences between the candidate device (IT / IF Control) and the predicate device (IT / IF Control).

TABLE B	SEBIA IT / IF CONTROL K130500	SEBIA IT / IF CONTROL
Intended Use	The IT / IF Control is designed to quality control the qualitative detection and characterization of human monoclonal immunoglobulins (Ig G, Ig A, Ig M, Kappa and Lambda) with the electrophoresis methods: - Immunotyping performed using capillary electrophoresis on SEBIA CAPILLARYS 2 and CAPILLARYS 2 FLEXPIERCING instruments and on SEBIA MINICAP instrument, - Immunofixation methods : SEBIA HYDRAGEL IF, HYDRAGEL IF Penta, HYDRAGEL BENCE JONES (Standard mask and Dynamic mask) performed using the HYDRASYS and HYDRASYS 2 instruments and the K20 electrophoresis chamber. The IT / IF Control is designed for laboratory use. It should be used (with its barcode label for CAPILLARYS and MINICAP procedures) like a human serum sample. The electrophoretic pattern obtained is specific for each batch of IT / IF control. For *In Vitro* Diagnostic Use.	The IT / IF Control is designed to quality control the qualitative detection and characterization of human monoclonal immunoglobulins (Ig G, Ig A, Ig M, Kappa and Lambda) with the electrophoresis methods: - Immunotyping performed using capillary electrophoresis on SEBIA CAPILLARYS 2, CAPILLARYS 2 FLEXPIERCING, CAPILLARYS 3 TERA instruments and on SEBIA MINICAP instrument, - Immunofixation methods : SEBIA HYDRAGEL IF, HYDRAGEL IF Penta, HYDRAGEL BENCE JONES (Standard mask and Dynamic mask) performed using the HYDRASYS and HYDRASYS 2 instruments and the K20 electrophoresis chamber. The IT / IF Control is designed for laboratory use. It should be used (with its barcode label for CAPILLARYS and MINICAP procedures) like a human serum sample. The electrophoretic pattern obtained is specific for each batch of IT / IF control. For *In Vitro* Diagnostic Use
Product Number	4788	4788
Format	1 vial (1.0 mL)	Same
Preparation	Reconstitute the lyophilized control vial with 1.0 mL of distilled or deionized water.	Same
Storage temperature	Before reconstitution, the lyophilized control must be stored between 2 °C and 8 °C. They are stable until the expiration date indicated on the vial labels.	Same
Shelf life	3 years at 2 - 8°C	4 years at 2 - 8°C

TABLE B	SEBIA IT / IF CONTROL K130500	SEBIA IT / IF CONTROL
In use storage	After reconstitution, the control is stable for 2 months maximum between - 18 °C and - 30 °C. Do not freeze and thaw the reconstituted control more than 20 times.	After reconstitution, the control is stable for 6 months maximum between - 18 °C and - 22 °C. Do not freeze and thaw the reconstituted control more than 20 times.

3. **Performance Data**:

a. Repeatability

Six (6) different serum samples, including 1 normal serum sample and 5 pathological serum samples with monoclonal components were run using the CAPI 3 IMMUNOTYPING 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, antiIg 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

Six (6) different serum samples, including 1 normal serum sample and 5 pathological serum samples with monoclonal components were run using the CAPI 3 IMMUNOTYPING 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 serum with three pathological serum samples all exhibiting monoclonal components and analyzed using the CAPI 3 IMMUNOTYPING procedure on CAPILLARYS 3 TERA instrument.

The results are summarized below:

Sample No.	Monoclonal component			Detection limit (mg/dL)
		Type	Concentration (g/dL)	
1	Ig G, L	Gamma	3.96	30.9
		Lambda		30.9
2	Ig A, K	Alpha	3.40	13.3
		Kappa		13.3
3	Ig M, K	Mu	1.60	25.0
		Kappa		25.0

d. Interferences

Studies were performed to assess common or known substances that could interfere with the CAPI 3 IMMUNOTYPING procedure performed with the CAPILLARYS 3 TERA instrument. The interfering substances were evaluated in 4 different serum samples (1 normal serum sample and 3 pathological serum samples with monoclonal component).
Samples containing potential interferents were tested and the results were compared to those obtained from control samples containing no potential interfering substances.

No interference with the CAPI 3 IMMUNOTYPING procedure was detected due to the serum sample's high concentration of the following interfering factors tested at levels equal to the concentrations listed below:

Interfering factor	Concentration
Triglycerides	3.59 g/dL (41 mM)
Bilirubin	20 mg/dL (342 µM)
Rheumatoid factor	981 IU/mL
Hemoglobin	0.2 g/dL

Inference studies were performed according to the Clinical Laboratory Standards Institute (CLSI - USA) EP7-A2 guideline "Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition".

~~e.~~ Method Comparison

A method comparison studies were conducted using a total of 115 serum samples (12 normal serum samples and 103 pathological serum samples).
Samples were analyzed in singlicate using the CAPI 3 IMMUNOTYPING procedure on the CAPILLARYS 3 TERA instrument (candidate device) and the CAPILLARYS IMMUNOTYPING procedure (predicate device).

i. Study

A total of 115 serum samples (12 normal serum samples and 103 pathological serum samples).
This study demonstrated a 100 % agreement between the two techniques:
• For the 12 normal serum samples: complete agreement (concordance).
• For the 103 pathological serum samples: complete agreement (concordance).
In all cases, both techniques detected and characterized the monoclonal proteins (immunotyping) in human serum with complete agreement (see results below).

Qualitative Results	Number of serum samples	Complete Agreement
Normal	12	Complete Agreement
Ig G, Kappa	37	Complete Agreement
Ig G, Lambda	27	Complete Agreement
Ig A, Kappa	6	Complete Agreement
Ig A, Lambda	4	Complete Agreement
Ig M, Kappa	14	Complete Agreement
Ig M, Lambda	4	Complete Agreement
2 Ig A, Kappa	3	Complete Agreement
2 Ig M, Kappa	2	Complete Agreement
Ig G, Kappa + Ig G, Lambda	2	Complete Agreement
2 Ig A, Kappa + Ig G, Kappa	1	Complete Agreement
Ig G, Kappa + Ig A, Kappa + Ig M, Lambda	1	Complete Agreement
2 Lambda free	1	Complete Agreement
1 Kappa free	1	Complete Agreement
Grand Total	**115**	Complete Agreement

4. Conclusion:

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