K130500

CAPILLARYS IMMUNOTYPING & CAPILLARYS 2 / CAPILLARYS 2 FLEX PIERCING instrument
IT / IF CONTROL & CAPILLARYS 2

July 2013

JUL 26 2013

510k SUMMARY

INTENDED USE AND SUMMARY OF THE IMMUNOTYPING PROCEDURES

The CAPILLARYS IMMUNOTYPING kit is designed for the detection and the characterization of monoclonal proteins (immunotyping) in human urine and serum with the CAPILLARYS 2 and CAPILLARYS 2 FLEX PIERCING instruments, for capillary electrophoresis. It is used in conjunction with the CAPILLARYS PROTEIN(E) 6 kit, SEBIA, designed for proteins separation into 6 major fractions in alkaline buffer (pH 9.9).
The CAPILLARYS 2 and CAPILLARYS 2 FLEX PIERCING instruments 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.

INTENDED USE AND SUMMARY OF IT/IF CONTROL PROCEDURES

The IT / IF Control is designed to quality control the qualitative the 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 FLEX PIERCING 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.

PRINCIPLES OF THE IMMUNOTYPING TEST

The principles of the test of Sebia CAPILLARYS IMMUNOTYPING kit using the CAPILLARYS 2 instrument and CAPILLARYS 2 FLEX PIERCING instrument are described in Section IV in the performance standards of this submission and the test details are presented in the product package insert included with each kit in Section III (labeling).

The Sebia CAPILLARYS IMMUNOTYPING reagent kit was cleared in prior 510K submission, K042939 using serum samples and K082085 using urine samples. Electrophoresis is a process for the identification of monoclonal proteins (M-proteins, paraproteins, monoclonal immunoglobulins) that are detected as abnormal fraction(s) in the serum or urine protein electrophoresis primarily in the beta globulin and gamma globulin zones. Immunotyping procedure allows for specific identification of such immunoglobulin proteins. The proteins migrate through a buffered capillary at a specific pH. Separation occurs according to the electrolyte pH and electroosmotic flow. Specific antisera (IgG, IgA, IgM, Kappa and Lambda) are mixed with the sample. A reference pattern is compared with the patterns obtained after individual immunoglobulin classes and types have been eliminated from the serum or urine sample in reactions with specific antisera.

A. This submission is to support the use of *CAPILLARYS IMMUNOTYPING with the device CAPILLARYS 2 instrument*, with serum and urine samples. The reagents CAPILLARYS IMMUNOTYPING were previously cleared in submissions K042939 and K082085.

B. This submission also includes supporting data for the *IT / IF Control with the device CAPILLARYS 2 instrument*, using the CAPILLARYS IMMUNOTYPING reagents.

The IT/IF control was cleared in prior 510K submissions, K101863. The results of the IT/IF control using the CAPILLARYS 2 instrument with the CAPILLARYS IMMUNOTYPING – procedure was compared to the Beckman Paragon CZE 2000 IFE/s Control which was cleared, K002799

C. This submission will demonstrate the *CAPILLARYS IMMUNOTYPING with the CAPILLARYS 2 instrument compared to the CAPILLARYS 2 FLEX PIERCING instrument*, with serum and urine samples. This study presents the equivalence of both instruments (CAPILLARYS 2 and CAPILLARYS 2 FLEX PIERCING).

   The reagents CAPILLARYS IMMUNOTYPING were previously cleared in submissions K042939 and K082085.

   The CAPILLARYS 2 FLEX PIERCING instrument was 510K cleared, K112550, May 25 2012 for CAPILLARYS HEMOGLOBIN(E). The CAPILLARYS 2 FLEX PIERCING instrument was also 510K cleared, K122101, for CAPILLARYS HbA1c.

SUBJECTS OF THIS 510(k) PREMARKET NOTIFICATION

This submission includes:

1) CAPILLARYS IMMUNOTYPING (PN 2100) with the device CAPILLARYS 2 instrument (PN 1222) for serum and urine samples. The CAPILLARYS IMMUNOTYPING KIT was cleared in prior 510K submissions.

2) IT / IF Control (PN 4788) with the new device CAPILLARYS 2 instrument (PN 1222). The IT / IF Control was cleared in prior 510K submissions.

3) CAPILLARYS IMMUNOTYPING (PN 2100) with the device CAPILLARYS 2 FLEX PIERCING instrument (PN 1227) for serum and urine samples. The CAPILLARYS IMMUNOTYPING KIT was cleared in prior 510K submissions

REGULATORY STATUS

The CAPILLARYS IMMUNOTYPING and IT / IF CONTROL using the CAPILLARYS 2 Instrument/ CAPILLARYS 2 FLEX PIERCING instruments are classified by FDA as Class II device. Sebia is seeking clearance to import the CAPILLARYS 2 and CAPILLARYS 2 FLEX PIERCING device described above, and by this submission is notifying FDA of its intent to market these products in the United States.

510K Table of Predicate Devices

Predicate Devices	510K	Sample Type	Clearance date
HYDRAGEL IF kits	K960669	Serum	July 12, 1996
CAPILLARYS IMMUNOTYPING	K042939	Serum	June 27, 2005
CAPILLARYS IMMUNOTYPING	K082085	Urine	April 17, 2009
IT/IF Control	K101863	Serum/ Urine	November 7, 2011
Paragon CZE 2000 IFE/s Control	K002799	Serum/Urine	October 5, 2000

Supporting labeling can be found in section IV that includes the package insert labeling of the prior cleared products and predicate devices.

PRODUCT DESCRIPTION

1. CAPILLARYS 2 instrument, Part Number 1222

2. CAPILLARYS 2 FLEX PIERCING instrument, Part Number 1227

3. Reagent Kits

The configurations of the CAPILLARYS IMMUNOTYPING kits consist of the components summarized in Tables I and II. Additional details are provided in Package Inserts included in Section III of the submission. Each kit with instrument is supplied with Package Insert/manual

which contains instruction for use and all the necessary information on the components needed to run the test that are sold separately. Each Package insert also contains information on storage conditions, shelf-life and signs of deterioration of the kit components and the reagents sold separately.

TABLE I. REAGENTS AND MATERIALS SUPPLIED IN THE CAPILLARYS IMMUNOTYPING KIT (PN 2100) presented in prior 510K submissions

ITEM	PN 2100	510K file with reagent supporting data	Sample Type
CAPILLARYS IMMUNOTYPING segments	60 ea.	K042939	Serum
CAPILLARYS IMMUNOTYPING segments	60 ea.	K082085	Urine

ITEM	PN 4788	510K file with reagent supporting data	Matrix of Control
IT/IF Control	1 vial, 1mL ea.	K101863	Serum based

TABLE II. REAGENTS AND MATERIALS REQUIRED BUT NOT SUPPLIED IN THE CAPILLARYS IMMUNOTYPING KIT which were presented in prior 510K submissions

ITEM	PN	Components	510K file with reagent supporting data
CAPILLARYS PROTEIN(E) 6 kit	2003	2 vials, 700mL ea.	K042939, K082085
Capiclean	2051	1 vial, 12mL.	K042939, K082085
CAPILLARYS wash solution	2052	2 vials, 70mL ea.	K042939, K082085

LABELING

Labeling is described in Section III.

A. CAPILLARYS 2 instrument operators manual
B. CAPILLARYS IMMUNOTYPING package insert
C. IT / IF CONTROL package insert
D. CAPILLARYS 2 FLEX PIERCING instrument operators manual
E. PHORESIS software

COMPARISON (CONCORDANCE), SUBSTANTIAL EQUIVALENCE AND PERFORMANCE STUDIES

A. **The performance and comparative studies of the CAPILLARYS IMMUNOTYPING KIT used with the CAPILLARYS 2 instrument for serum and urine specimens** were performed using Sebia's commercially available materials and standard procedures. Comparative studies were conducted with the predicate devices, Sebia HYDRAGEL IF kit, K960669.
The CAPILLARYS IMMUNOTYPING on the CAPILLARYS 2 Instrument for serum and urine specimens was found, experimentally and conceptually, substantially equivalent in assay principle, function, use, safety and effectiveness to predicates: Sebia HYDRAGEL IF kit using the Hydrasys instrument.

B. **The performance and comparative studies of the IT/IF Control using the CAPILLARYS IMMUNOTYPING kit with CAPILLARYS 2 instrument** was compared to the predicate device, Paragon CZE 2000 IFE/s Control, K002799. The IT/IF control was found, experimentally and conceptually, substantially equivalent in assay, principal, function, use, safety and effectiveness to the predicate: Paragon CZE 2000 IFE/s Control.

C. **The performance and comparative studies of the CAPILLARYS IMMUNOTYPING KIT used with the CAPILLARYS 2 instrument compared to the CAPILLARYS 2 FLEX PIERCING instrumen for serum and urine specimens.**
The CAPILLARYS IMMUNOTYPING on the CAPILLARYS 2 FLEX PIERCING Instrument was found substantially equivalent in assay, principle, function, use and safety and effectiveness to the CAPILLARYS 2 instrument for serum and urine samples.

STANDARDS

At the present time no performance standards exist for this type of *In Vitro Diagnostic* test (Section VII).

STATEMENT OF MANUFACTURE AND MANUFACTURING CONTROLS

The CAPILLARYS 2 and CAPILLARYS 2 FLEX PIERCING instrument, reagent kits and accessories are manufactured by Sebia in accordance with applicable GLP and GMP/Quality System practices and Sebia's own specifications, in their entirety at its manufacturing facility located at:

Parc Technologique Léonard de Vinci
Rue Léonard de Vinci,
CP 8010 LISSES, 91008 EVRY Cedex
FRANCE

All raw materials are obtained by Sebia from qualified suppliers.

Sebia adheres to a system of incoming, in process and finished product quality control procedures.

Sebia has been certified against ISO 9001 / ISO 13485.

The CAPILLARYS IMMUNOTYPING KIT USING THE CAPILLARYS 2 and IT/IF control devices are for *In Vitro Diagnostic Use*.
The CAPILLARYS IMMUNOTYPING KIT USING THE CAPILLARYS 2 FLEX PIERCING devices are for *In Vitro Diagnostic Use*.

Sebia's corporate office is located at:

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

In the United States the product will be distributed by:

SEBIA, Inc.
400-1705 Corporate drive, Norcross GA 30093
Phone 770 446-3707; Fax 770 446-8511

MARKETING INFORMATION

Sebia's CAPILLARYS IMMUNOTYPING KIT USING THE CAPILLARYS 2 AND IT/IF CONTROL and CAPILLARYS IMMUNOTYPING KIT USING THE CAPILLARYS 2 FLEX PIERCING will be offered for sale in the United States to the following market segments/users:

1. Hospital clinical diagnostic laboratories
2. Private diagnostic laboratories
3. Reference diagnostic laboratories

Sebia's products are currently being sold to the above type of diagnostic laboratories worldwide.

PREMARKET NOTIFICATIONS

Signed and dated "519(k) Statement" and "Truthful and Accurate Statement" are included in this 510(k) submission (Section X and XI)

INDICATION FOR USE FORM

The IFU form is included in this 510(k) submission for the CAPILLARYS IMMUNOTYPING KIT and the IT/IF CONTROL.

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

July 26, 2013

SEBIA INC.
C/O MS. KAREN ANDERSON, MT (ASCP)
DIRECTOR OF TECHNICAL TRAINING AND QUALITY ASSURANCE
SUITE 400
1705 CORPORATE DRIVE
NORCROSS GA 30093

Re: K130500
Trade/Device Name: CAPILLARYS IMMUNOTYPING (PN 2100) and IT/ IF CONTROL (PN4788) using the CAPILLARYS 2 Instrument (PN 1222) and CAPILLARYS 2 FLEX-PIERCING Instrument (PN 1227)
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: II
Product Code: CFF, DFH, DEH, CEF, JJY
Dated: July 22, 2013
Received: July 25, 2013

Dear Ms. 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: CAPILLARYS IMMUNOTYPING

Indications for 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.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130500

Indications for Use

510(k) Number (if known): k130500

Device Name: IT / IF CONTROL

Indications for Use:

The IT / IF Control is designed to quality control the qualitative the 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 FLEX PIERCING 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.

Prescription Use X	And/Or	Over the Counter Use.
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k130500