510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k101863

B. Purpose for Submission:
New device

C. Measurand:
Quality Control for Monoclonal Immunoglobulins (IgG, IgA, IgM, Kappa, Lambda)

D. Type of Test:
Assayed quality control material

E. Applicant:
SEBIA INC, USA

F. Proprietary and Established Names:
IT/IF Control

G. Regulatory Information:

1. Regulation section:
   21 CFR §862.1660 – Quality Control Material (Assayed and Unassayed)
   21 CFR §866.5510 – Immunoglobulins A, G, M, D, and E Immunological Test System
   21 CFR §866.5550 – Immunoglobulin (Light Chain Specific) Immunological Test System
2. Classification:
   Class I Reserve (control); Class II (test system);
3. Product code:
   JJY – Multi-Analyte Controls, All Kinds (Assayed)
   CFF – Immunoelectrophoretic, Immunoglobulins (G, A, M)
   DFH – Kappa, Antigen, Antiserum, Control
   DEH – Lambda, Antigen, Antiserum, Control
4. Panel:
   Immunology (82); Chemistry (75)

H. Intended Use:

1. Intended use:
   The IT/IF Control is designed for the qualitative quality control of the detection and characterization of human monoclonal immunoglobulins (IgG, IgA, IgM, Kappa and Lambda) with the electrophoresis methods:
   - Immunotyping performed using capillary electrophoresis 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 MINICAP procedure) like a human serum sample.

   The electrophoretic pattern obtained is specific for each batch of IT/IF control.

   For *in vitro* diagnostic use.

2. Indication(s) for use:
   Same as Intended use.
3. Special conditions for use statement(s):
   For prescription only.
4. Special instrument requirements:
   This device has been validated for use with the following SEBIA instruments:
   - MINICAP System (capillary electrophoresis) cleared in k073002
   - HYDRASYS 1 and HYDRASYS 2 (IF) cleared in k960029
   - HYDRASYS 1 Focusing and HYDRASYS 2 Focusing (IF) cleared in k033277
   - HYDRASYS 2 Scan cleared in k960029
   - HYDRASYS 2 Scan Focusing cleared in k033277
   - HYDRASYS 2 Isofocusing cleared in k063498
   - SEBIA K20 electrophoresis chamber (IF) cleared in k951536

I. Device Description:

The IT/IF Control is obtained from a pool of human sera complemented with monoclonal immunoglobulins displaying the 5 specificities G, A, M, Kappa and Lambda.
The IT/IF Control is supplied in a stabilized lyophilized form.

J. Substantial Equivalence Information:

1. Predicate device name(s) and Predicate k number(s):
   Beckman Paragon CZE® IFE/s Control 2000, k002799
2. Comparison with predicates:

Similarities		
Item	Device	Predicate
Intended Use	For the detection and characterization of monoclonal immunoglobulins.	Same
Results	Qualitative Monoclonal Protein Interpretation	Same

Differences		
Item	Device	Predicate
Indication for Use/ Intended Use	The IT/IF Control is designed for the qualitative quality control for the detection and characterization of human monoclonal immunoglobulins (IgG, IgA, IgM, Kappa and Lambda) with the electrophoresis methods: - immunotyping performed using capillary electrophoresis on	Paragon CZE® 2000 IFE/s (Immunofixation Electrophoresis by subtraction) Control is for use with the Paragon CZE® 2000 system and related IFE/s reagents to assure correct immunosubtraction by the system. The Control provides a qualitative test to identify human IgG kappa, IgA lambda, IgM kappa proteins by

Differences		
Item	Device	Predicate
	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.	immunosubtraction.
Instrument(s)	Minicap Immunotyping (MiniCapillarys) instrument; Hydrasys and Hydrasys 2 electrophoresis instruments and the K20 electrophoresis chamber.	Paragon CZE® 2000 IFE/s
Matrix	Human serum	Human plasma
Form	Lyophilized	Liquid
Packaging and Volume	1 Bottle Reconstituted to 1 mL	3 Bottles x 3 mL each
Storage Stability	Lyophilized at 2-8°C for 3 years. Reconstituted aliqouts at 2-8°C for 1 week; Reconstituted aliqouts at -18 to -22°C for 2 months Frreze/ thaw cycle: 20 cycles	Unopened bottles at 2-8°C for 18 months. Opened bottles at 2-8°C for 45 days.
Preparation for Use	Use upon reconstitution	Use upon 1:2 dilution

K. Standard/Guidance Document Referenced (if applicable):

Not applicable.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Comparison with Predicate and Precision/Reproducibility studies:*
Two sets of aliquots of one lot of IT/IF control device were tested on IT capillaries and IFE gels (different IFE gel configurations in different SEBIA IFE instruments were used) as follows:
Minicap Immunotyping Instrument: IT/IF control was run 3 times on 2 capillaries within a run and the run was repeated with 3 different lots of antisera for 3 days. The new device displayed IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins in the Minicap capillary electrophoretograms. The identified monoclonal proteins were concordant and reproducible for the within-run and between-run IT Capillarys qualitative results.

HYDRASYS Systems (Hydrasys 1 & 2; Hydrasys Focusing 1 & 2; Hydrasys Scan Isofocusing 1 & 2): The SEBIA IT/IF control was run 3 times on 3 each of the 6 different gel configurations within a run and the run was repeated with 3 different lots of antisera for 3 days. The 6 different gel configurations were as follows: 4IF Acid Violet, 4IF Amido Black, 9IF Gel, 4 Bence Jones (BJ) Gel, 9 BJ Gel and 12 IF Penta Gel. The IT/IF control displayed IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins in their respective gel configurations. The identified monoclonal proteins were concordant and reproducible for the within-run and between run IF agarose gel qualitative results.

K20 electrophoresis chamber: The SEBIA IT/IF control was run 3 times on 3 sets of gels each of the 3 different gel configurations within a run and the run was repeated with 3 different lots of antisera for 3 days. The 2 different gel configurations were: IF Penta Gel; Single IF; Double IF. The IT/IF controls displayed IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins in their respective gel configurations. The identified monoclonal proteins were concordant and reproducible for the within-run and between run IF gel qualitative results.

b. *Linearity/assay reportable range:*
Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Unopened bottle accelerated stability study: Two lyophilized lots of SEBIA IT/IF control were tested upon storage at room temperature weekly at week 1, 2, 3, 4, 5, 6, 7, 8 and 3 months. All IT/IF results met the qualitative acceptance criteria. Real time studies are ongoing to support the 3 year expiry dating indicated on the lyophilized bottles when stored at 2-8°C.

Open reconstituted bottle stability study: Two lots of SEBIA IT/IF control were reconstituted and then stored at different temperatures (2-8°C, -18 to -22°C) for different periods of time before the testing. For 2-8°C stability study, scheduled target testing dates were week 1, 2, 3, 4, 5 and 6. For -18 to -22°C stability study, scheduled target testing dates were week 1; week 4; week 8 or 2 months, and 3 months. In addition, freeze/thaw studies were performed by storing frozen control aliquots at -18 to -22°C then thawed and refrozen weekly for a total of 30 cycles at the following cycle intervals: 1, 5,

8, 11, 13, 15, 16, 20, and 30. All IT and IF results met the qualitative acceptance criteria. Open reconstituted control bottle stability claims are: 1 week at 2-8°C; 2 months at -18 to -22°C; and freeze/thaw for no more than 20 cycles within 2 months of reconstitution when stored at -18 to -22°C.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Two aliquots of one lot of IT/IF control device and two aliquots of one lot of Beckman IFE control were tested on both IT capillaries and IFE gels (different IFE gel configurations in different SEBIA IFE instruments were used) as follows:
Minicap Immunotyping Instrument: Control aliquots were run 3 times on 2 capillaries within a run and the run was repeated with 3 different lots of antisera for 3 days. Both the new and predicate controls identified the IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins and were concordant in the Minicap IT capillary electrophoretograms.

HYDRASYS Systems (Hydrasys 1 & 2; Hydrasys Focusing 1 & 2; Hydrasys Scan Isofocusing 1 & 2): Control aliquots were run 3 times on 3 each of the 6 different gel configurations within a run and the run was repeated with 3 different lots of antisera for 3 days. The 6 different gel configurations were as follows: 4IF Acid Violet, 4IF Amido Black, 9IF Gel, 4 Bence Jones (BJ) Gel, 9 BJ Gel and 12 IF Penta Gel. Both new and predicate controls identified the IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins and were concordant in all the different gel configurations.

K20 electrophoresis chamber: Control aliquots were run 3 times on 3 sets of gels each of the 3 different gel configurations within a run and the run was repeated with 3 different lots of antisera for 3 days. The 2 different gel configurations were: IF Penta Gel; Single IF; Double IF. One Beckman control was tested with the SEBIA control runs. The new and predicate controls identified the IgG Lambda, IgA Lambda, and IgM Kappa monoclonal proteins and were concordant in all the different gel configurations.

b. Matrix comparison:
Not applicable.

3. Clinical studies:

a. Clinical Sensitivity and specificity:
Not applicable.

b. Other clinical supportive data (when a. is not applicable):
Not applicable.

4. Clinical cut-off**:**
Not applicable.

5. Expected values/Reference range:
   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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