

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

K040925

B. Purpose for Submission:

New device

C. Analyte:

Albumin, alpha-1 globulins, alpha-2 globulins, beta-1 globulins, beta-2 globulins, gamma globulins

D. Type of Test:

Quality Control Material

E. Applicant:

Sebia Inc.

F. Proprietary and Established Names:

Sebia Normal Control Serum

Sebia Hypergamma Control Serum

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1660
2. Classification:
Class I
3. Product Code:
JJY
4. Panel:
75

H. Intended Use:

1. Intended use(s):

Sebia Normal Control Serum is indicated for the quality control of densitometric quantification of electrophoretic separations of human serum proteins, lipoproteins and lipoprotein-cholesterol fractions on Sebia HYDRAGEL™, agarose gels. The Normal Control Serum is also indicated for the quality control of quantification of electrophoretic separations of human serum proteins on Sebia CAPILLARYS™, the capillary electrophoresis system.

The constituents of the Normal Control Serum are within the concentration ranges (g/dL) expected in normal individuals. The relative (%) distribution of individual fractions and the densitometric profile also reflect normal distribution.

Sebia Hypergamma Control Serum is indicated for the quality control of densitometric quantification of electrophoretic separations of human serum proteins on HYDRAGEL™ agarose gels and for the quality control of quantification of electrophoretic separations of human serum proteins on Sebia CAPILLARYS™, the capillary electrophoresis system. The

concentration of gammaglobulins in this control is elevated above the normal level.

2. Indication(s) for use:
Same as above
3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
Values are listed for each analyte.

I. Device Description:

The Sebia Normal Control Serum and the Sebia Hypergamma Control Serum are presented in a lyophilized form. There are five vials of control serum per package (box). Each box is supplied with Package Insert/Instruction sheet that contains instruction for use, information on storage conditions and shelf life. Each package insert provide ranges of assayed densitometric control values (relative percent mean \pm 2 S.D.) for individual analytes (electrophoretic fractions).

J. Substantial Equivalence Information:

1. Predicate device name(s):
BioRad Liquicheck Controls
2. Predicate K number(s):
K903430
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Normal and Hypergamma Control Serums	BioRad Liquicheck Controls
Intended Use	Control sera for electrophoretic based tests and quantification of the resulting migration patterns by densitometry	Control sera for electrophoretic based tests and quantification of the resulting migration patterns by densitometry
Matrix	Human serum based	Human serum based
Storage	- 20° C or colder	- 20° C or colder
Differences		
Item	Device	Predicate
Form	Lyophilized	Frozen

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

None referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

- Not applicable
- b. *Linearity/assay reportable range:*
Not applicable
- c. *Traceability (controls, calibrators, or method):*
The mean values were derived from repetitive measurements ± 2 SD. The electrophoretic separations on HYDRAGEL gels of the various human serum components constituting the control sera are first visualized by appropriate means that are specific for each type of test. The visualized electrophoretic separations are then subjected to densitometry. The densitometric values for the individual electrophoretic fractions of interest form the basis for calculating the control values. The serum protein fractions separated on CAPILLARYS are measured directly by their absorbance at 200 nm.
- 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:*
Not applicable
 - b. *Matrix comparison:*
Not applicable
- 3. Clinical studies:
 - a. *Clinical sensitivity:*
Not applicable
 - b. *Clinical specificity:*
Not applicable
 - c. *Other clinical supportive data (when a and b are not applicable):*
Not applicable
- 4. Clinical cut-off:
Not applicable
- 5. Expected values/Reference range:
Not applicable

N. Conclusion:

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